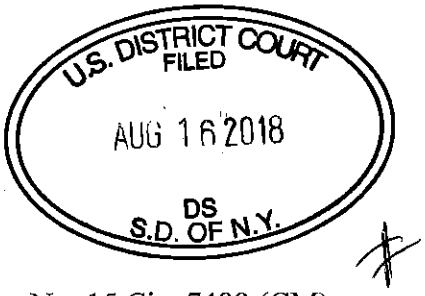

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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IN RE NAMENDA DIRECT PURCHASER ANTITRUST LITIGATION

No. 15 Civ. 7488 (CM)

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MEMORANDUM DECISION AND ORDER DENYING DEFENDANTS' MOTION FOR SUMMARY JUDGMENT; GRANTING IN SUBSTANTIAL PART AND DENYING IN PART DEFENDANTS' *DAUBERT* MOTIONS TO EXCLUDE OPINIONS AND TESTIMONY OF PLAINTIFFS' EXPERTS; AND GRANTING PLAINTIFFS' MOTION FOR CLASS CERTIFICATION

McMahon, C.J.:

Plaintiffs J.M. Smith Corporation d/b/a Smith Drug Company ("Smith") and Rochester Drug Co-Operative, Inc. ("RDC") (collectively, "Direct Purchaser Plaintiffs" or "Plaintiffs") commenced this antitrust suit on behalf of themselves and a putative class of similarly situated purchasers of Namenda. Plaintiffs allege that Defendants – Actavis PLC (now known as Allergan PLC), Forest Laboratories, LLC, Forest Laboratories, Inc., and Forest Laboratories Holdings Ltd. (collectively, "Forest" or "Defendants") – schemed to delay entry of generic versions of an Alzheimer's disease treatment by entering into collusive settlements with various generic drug companies and attempting a hard switch in violation of sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2 (2016).

Namenda® ("Namenda") is a branded drug used to treat moderate to severe stages of Alzheimer's, a neurodegenerative brain disease that causes memory loss, among other symptoms. Forest had a license to market both Namenda IR (immediate release), a twice-daily drug, and Namenda XR (extended release), a once-daily drug, in the United States under U.S. Patent No. 5,061,703 (the "'703 Patent"). (Am. Compl. ¶ 2, Dkt. No. 29.)

Plaintiffs allege that Forest engaged in a two-part anticompetitive scheme to improperly block generic competition for Namenda IR by: (1) conspiring with manufacturers of generic versions of Namenda IR to drop their legal challenges to the '703 Patent and delay launch of generic versions of Namenda IR until an identical date three months after the expiration of the '703 Patent; and (2) using this improperly obtained period of additional exclusivity to launch the successor branded product, Namenda XR, in order to force the conversion of the market from Namenda IR to the clinically equivalent Namenda XR (hereinafter the "hard switch") before market entry of the generic versions of Namenda IR. (*See id.* at ¶ 5.) Here, Plaintiffs allege that Defendants' illegal hard switch strategy included prematurely removing Namenda IR from the market before its patent expiration such that only Namenda XR would be available for purchase in the months before Forest faced generic competition for Namenda IR. Plaintiffs allege Defendants knew that, given the nature of Alzheimer's treatment, once a patient was on Namenda XR, there was a decreased likelihood that the patient would "reverse commute" back to a generic version of Namenda IR after cheaper generic versions of the drug became available.

Presently before the Court are two motions: Defendants' motion for summary judgment on all claims in Direct Purchaser Plaintiffs' First Amended Complaint (Dkt. No. 434) and Plaintiffs' motion to certify this as a class action. (Dkt. No. 400.) For the reasons set forth below, Defendants' motion for summary judgment is DENIED, and Plaintiffs' motion for class certification is GRANTED.

Additionally, Defendants have filed six separate motions to exclude the opinions and proposed testimony of Plaintiffs' experts (*see* Dkt. Nos. 437, 439, 441, 443, 445, 505), each of which is addressed below.

I. *DAUBERT* MOTIONS

Before I recount the facts, I must consider exactly what should and should not be part of the record on Defendants' motion for summary judgment. "If the expert testimony is excluded as inadmissible, the court must make the summary judgment determination without that evidence." *Water Pollution Control Auth. of City of Norwalk v. Flowserve US Inc.*, No. 3:14 Civ. 00549 (VLB), 2018 WL 1525709, at *5 (D. Conn. Mar. 28, 2018).

Defendants have moved to exclude the opinions and proposed testimony of: (1) Janet K. DeLeon (Dkt. No. 437); (2) Professor Einer Elhauge (Dkt. No. 439); (3) Dr. Russell Lamb (Dkt. No. 445); (4) Dr. Ernest Berndt and Dr. Russell Lamb regarding their use of forecast averages (Dkt. No. 441); (5) John R. Thomas, Esq. (Dkt. No. 505); and (6) George W. Johnston, Esq. (Dkt. No. 443).

The Daubert Standard

"On a summary judgment motion, the district court properly considers only evidence that would be admissible at trial." *Nora Beverages, Inc. v. Perrier Grp. of Am., Inc.*, 164 F.3d 736, 746 (2d Cir. 1998) (citing *Raskin v. Wyatt Co.*, 125 F.3d 55, 66 (2d Cir. 1997)). Whether expert evidence should be admitted on a motion for summary judgment is a matter committed to the district court's "broad discretion." *Yurman Design, Inc. v. PAJ, Inc.*, 29 F. App'x 46, 48 (2d Cir. 2002) (internal citation and quotation marks omitted); *see also Nora Beverages, Inc.*, 164 F.3d at 746.

Under Rule 702 of the Federal Rules of Evidence, which codifies the standard for admissibility set forth by *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the court's role is to determine whether the "expert" is qualified to testify as an expert. Rule 702 provides:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702.

"The proponent of the expert testimony has the burden to establish the [Rule 702] admissibility requirements, with the district court acting as a gatekeeper to ensure that the expert's testimony both rests on a reliable foundation and is relevant to the task at hand." *Novick v. AXA Network, LLC*, 714 F. App'x 22, 25 (2d Cir. 2017) (citing *In re Pfizer Inc. Sec. Litig.*, 819 F.3d 642, 658 (2d Cir. 2016)) (internal citation omitted); *see also United States v. Apple, Inc.*, 791 F.3d 290, 335 n.24 (2d Cir. 2015) (citing *United States v. Williams*, 506 F.3d 151, 160 (2d Cir. 2007)).

Though the Rule "embodies a liberal standard of admissibility," *Nimely v. City of New York*, 414 F.3d 381, 395 (2d Cir. 2005), "when an expert opinion is based on data, a methodology, or studies that are simply inadequate to support the conclusions reached, *Daubert* and Rule 702 mandate the exclusion of that unreliable opinion testimony." *Cedar Petrochemicals, Inc. v. Dongbu Hannong Chem. Co.*, 769 F. Supp. 2d 269, 282 (S.D.N.Y. 2011) (internal citations omitted). "In *Daubert*, the United States Supreme Court confirmed that trial courts should serve as sentries, preventing juries from being overwhelmed by unsupportable speculation cloaked as expertise." *Id.* at 281 – 82.

Furthermore, the Second Circuit has held that to "warrant admissibility . . . it is critical that an expert's analysis be reliable at every step." *United States v. Morgan*, 675 F. App'x 53, 55 (2d Cir. 2017), *cert. denied*, 138 S. Ct. 176 (2017) (internal citation omitted). Of course, "the district court must focus on the principles and methodology employed by the expert, without regard to the

conclusions the expert has reached or the district court's belief as to the correctness of those conclusions." *Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 266 (2d Cir. 2002) (internal citation omitted). Nevertheless, as the Supreme Court has recognized,

> conclusions and methodology are not entirely distinct from one another . . . [N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.

Id. at 266 (citing *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)).

Moreover, "The standard to evaluate non-scientific expert testimony is whether the expert bases testimony upon professional studies or personal experience and employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Louisiana Wholesale Drug Co. v. Sanofi-Aventis*, No. 07 Civ. 7343 (HB), 2008 WL 4580016, at *6 (S.D.N.Y. Oct. 14, 2008) (citing *Kumho Tire Ltd. v. Carmichael*, 526 U.S. 137 (1999)).

1. Janet K. DeLeon

Defendants move to exclude the opinions and testimony of Plaintiffs' expert, Janet K. DeLeon. The motion is GRANTED.

Plaintiffs offer Ms. DeLeon as an expert in the process of developing and launching a generic drug. Plaintiffs offer two reports from Ms. DeLeon: (1) an initial report dated September 15, 2017 (Hamburger Decl. Ex. 10, Dkt. No. 438 ("DeLeon Rep.")); and (2) a supplemental report dated October 23, 2017 (*Id.* at Ex. 11 ("DeLeon Supp. Rep.").) Ms. DeLeon was asked to answer the following question: whether there were any supply, equipment or manufacturing challenges that would have prevented five generic competitors – Amneal Pharmaceuticals, Dr. Reddy's Laboratories, Inc., Lupin Pharmaceuticals, Inc., Mylan Pharmaceuticals, Inc. ("Mylan"), and Sun Pharmaceutical Industries, Inc. – or Forest itself from launching a generic version of

Namenda IR prior to July 2015. (*See* DeLeon Rep. ¶ 6.) Her answer is that there were none. She rests her opinion on "[her] educational background, [her] professional experience, [her] knowledge and understanding of pharmaceutical industry practices, [U.S. Food and Drug Administration ("FDA")] regulations, guidelines, and enforcement policies, and publicly-available materials such as FDA MAPPs [Manual of Policies and Procedures] and Guidances." (*Id.* at ¶ 6.)

A. Qualifications

Ms. DeLeon's credentials certainly qualify her to offer an opinion on this question.

She has spent 30 years in the pharmaceutical industry, much of which was spent working on new drug launches, including specifically the launching of generics. She has sat on launch teams for 25 years. She has experience at Aventis as a liaison with external manufacturers of drug products and active ingredients, and she managed several applications to the FDA for approved products. At Beckloff, she helped companies develop new and generic drugs and get approval for them to go to market. Moreover, before starting her own pharmaceutical consultancy, Ms. DeLeon was Associate Director and then Director of Product Development at Cypress Pharmaceutical, Inc. and Hawthorn Pharmaceuticals, Inc. (together "Cypress") for seven years where she handled at least 12 separate drug launches. (*Id.* at ¶ 6.)

Her three decades of experience give her familiarity with both the drug launch process and with impediments to launch – including barriers to entry like supply, new technologies, or need for new equipment. In short, her credentials are impeccable.

B. Summary of Ms. DeLeon's Reports

Ms. DeLeon divides her analysis into three sections.

First, she explains, in considerable detail, the process for launching a new generic – a process with which she is intimately familiar – including the relevant regulatory and manufacturing background, and standard pharmaceutical industry practices employed in preparing for the launch of a new drug.

She then evaluates the extensive evidence derived during discovery about each generic's process leading up to the July 2015 launch of its generic Namenda IR. This revealed that each generic had followed precisely the launch process she outlined based on her own experience.

Finally, she opines – "based on her review of the evidence and [her] almost 30 years of pharmaceutical industry experience," – that nothing would have prevented the generic competitors from doing exactly the same thing as early as 2012. (*Id.* at ¶ 3.) She writes: "[I]n my opinion, there would have been no supply, equipment, or manufacturing challenges that would have prevented the Generics from launching their respective generic Namenda IR tablet products during that time period." (*Id.* at ¶ 23.) She continues, "I have seen no evidence in the record suggesting that Defendants could not have followed the same process and launched an authorized generic concurrently with the five Generics, if the Generics had a launch date any time between June 2012 and July 2015." (*Id.* at ¶ 28.)

In reaching her conclusions, Ms. DeLeon stressed that Namenda IR is categorized as a solid oral dose product, which is among the most common pharmaceutical products on the market; that immediate release tablets are among the easiest pharmaceutical products to manufacture; and that the supply of the active ingredient in Namenda IR (memantine hydrochloride) was readily available at all relevant times. (*See id.* at ¶ 3.)

Plaintiffs asked Ms. DeLeon to draft a supplemental report – in light of her review of additional documents and deposition testimony that became available after her initial report – in

which her opinions and conclusions about the generics' and Forest's ability to launch generic Namenda IR in 2012 did not change. (*See generally* DeLeon Supp. Rep.)

C. Analysis: Motion to Exclude Ms. DeLeon's Reports

Defendants' principal argument is that Ms. DeLeon's conclusions are highly speculative. The Court agrees that her opinion is little more than expert "*ipse dixit*." *Gen. Elec. Co. v. Joiner*, 552 U.S. 579, 591 (1993). As discussed below, the problem lies in the way Ms. DeLeon derived her opinion. It adds nothing to the direct evidence that cannot be elicited from fact witnesses – nothing other than the use of Ms. DeLeon's impressive credentials to bolster the credibility of those witnesses impermissibly.

Ms. DeLeon did not review in-house documents or deposition testimony from any of the generics or Forest to support her conclusion that the generics and Forest could have launched Namenda IR in 2012. Instead, she relies solely on her review of documents and testimony regarding the actual product launches by these parties in 2015. Defendants cite to several portions of Ms. DeLeon's deposition testimony in which she admitted as much. (*See* Hamburger Decl. Ex. 25, Dkt. No. 438 ("DeLeon Dep. Tr.") at 91:2 – 11; 143:24 – 144:8.)

Of course, Ms. DeLeon has a perfectly sensible and credible explanation for the lack of contemporaneous evidence; she specifically opines that drug companies place a low priority on tasks related to a drug that they cannot manufacture for a few years, so it was no surprise that they did not engage in pre-launch activity three years before they were permitted, by the terms of the settlements, to enter the generic market. (*See id.* at ¶ 36.)

Lacking the kind of evidence she was able to connect to the 2015 launches, Ms. DeLeon relied on three things in order to reach her conclusion about the lack of barriers to entry in 2012: the companies had been able to effectuate a normal launch, without experiencing any disruption

or challenge arising from supply, equipment or manufacturing issues, in July 2015; the companies were all major drug manufacturers with the capacity to have done exactly the same thing in earlier years; and a representative of each generic, testifying pursuant to Fed. R. Civ. P. 30(b)(6), had indicated under oath that his/her employer could in fact have undertaken the launch process for Namenda IR much sooner than it did.

According to Plaintiffs, Ms. DeLeon's conclusions are based on an application of her extensive experience in the pharmaceutical industry to the facts presented. However, Ms. DeLeon's experience is no substitute for "scientifically sound analysis." *United States v. Apple Inc.*, 952 F. Supp. 2d 638, 694 (S.D.N.Y. 2013), *aff'd*, 791 F.3d 290 (2d Cir. 2015).

Ms. DeLeon could have obtained data, from the generics or elsewhere, about matters that might have impacted the generics' ability to enter the market earlier: matters like whether there were any problems with the supply of drug ingredients in earlier years; whether there were equipment failures or manufacturing issues at any of the generics in 2011-12 (issues that apparently did not exist in 2014-15); whether the manufacturing capacity at those companies was already being used to manufacture other drugs such that it could not readily have been converted to Namenda at that time; and about whether Namenda IR would have been prioritized over those other drugs had there been a business reason to consider diverting manufacturing capacity to Namenda during earlier years.

Had Ms. DeLeon reviewed data of the above sort, and concluded, based on her substantial experience, that the generics (or some of them) could have launched as much as three years earlier, it would certainly have been within her expertise to so opine. But simply saying, "They could do it in 2015, so they could have done it in 2012," without any analysis of the market and corporate conditions that might have impacted the generics' ability to launch generic

Namenda in 2012, is a conclusion tethered to nothing whatever. This Court must exclude "unsupport[ed] speculation cloaked as expertise." *Cedar Petrochemicals, Inc. v. Dongbu Hannong Chem. Co.*, 769 F. Supp. 2d 269, 281 – 82 (S.D.N.Y. 2011).

To the extent that Plaintiffs point to the testimony of the generics' 30(b)(6) witnesses – all of whom testified that they could have launched generic Namenda as early as 2013 (not 2012) – to undergird Ms. DeLeon's opinion, their reliance exposes another problem with Ms. DeLeon's proposed testimony. Those fact witnesses can be called to testify at trial. They can repeat their testimony that their respective employers could have entered the generic Namenda market earlier but for the settlement of the patent suit. And they can offer an explanation, grounded in the actual circumstances facing each individual generic, about why that was so. Plaintiffs can then argue that the patent settlements were anticompetitive, and the trier of fact can accept or reject that argument after evaluating the credibility of these witnesses.

"[T]he amended Rules of Evidence require that expert testimony be based on 'sufficient facts or data' and on 'reliable principles and methods' that the expert 'witness has applied reliably to the facts of the case.'" *United States v. Dukagjini*, 326 F.3d 45, 54 (2d Cir. 2003) (citing Fed. R. Evid. 702). Here, the only thing that Ms. DeLeon's "expert" opinion does is bolster the credibility of the 30(b)(6) witnesses – misleading the trier of fact into thinking that, if an "expert" like Ms. DeLeon accepts the testimony of the 30(b)(6) witnesses, so should it. That is not the province of an expert; indeed, it is an arrogation of the function of the trier of fact. *See Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 266 (2d Cir. 2002). While Ms. DeLeon's experience might make her capable of assessing Defendants' adherence to "standard pharmaceutical industry practice," that experience does not transform her into an oracle.

(DeLeon Dep. Tr. at 109:1 – 4.) Her opinions and testimony are inadmissible and will not be considered on the motion for summary judgment.

2. Professor Einer Elhauge

Defendants move to exclude the opinions and testimony of Plaintiffs' expert, Professor Einer Elhauge, who opines in support of Plaintiffs' theory that the reverse payment from Forest to Mylan delayed generic entry. In the professor's opinion, without a reverse payment to generic competitors, the generic competitors would have entered the market on November 2, 2012, approximately 26.3 months earlier than they did.

Plaintiffs offer Revised Expert Report of Professor Einer Elhauge dated September 20, 2017 (Hamburger Decl. Ex. 1, Dkt. No. 438 ("Elhauge Rep.").) Plaintiffs retained Professor Elhauge to address, among other things, what economic analysis reveals about Forest and Mylan's settlement of the Namenda IR patent litigation. He was asked to opine on: (a) whether an alleged reverse payment from Forest to Mylan delayed generic entry into the market; (b) what the settlement entry date would have been in a no-payment settlement; (c) whether a reverse payment was reasonably necessary and the least restrictive means to achieve a settlement between Forest and Mylan; and (d) whether there were any procompetitive justifications for the reverse payment. (*See* Elhauge Rep. ¶ 1.) Professor Elhauge was asked to model a but-for world "with no payment." (Hamburger Decl. Ex. 14, Dkt. No. 438 ("Elhauge Dep. Tr.") at 80:11 – 17.)

A. Qualifications

Professor Elhauge is the Petrie Professor of Law at Harvard Law School, where he teaches and writes about the economic analysis of antitrust law, health policy, and various other subjects. (*See Elhauge Rep.* ¶ 3.) He has authored and co-authored several leading antitrust casebooks, and written articles on monopolization, bundled discounts, loyalty discounts, and

reverse-payment settlements. (*See id.*) Professor Elhauge has served as an expert on antitrust economics before Congress, arbitration panels, and foreign competition agencies. He has also testified as an expert witness on antitrust economics in dozens of federal cases. (*See id.* at ¶ 4.)

B. Summary of Professor Elhauge's Reports

Professor Elhauge begins by summarizing the settlement agreement, signed on July 21, 2010, between Forest and Mylan, which resulted in Mylan dropping its challenge to the Namenda IR patent. (*See* Elhauge Rep. ¶¶ 6 – 11.) He then estimates the parties' actual bargaining strength based on the settlement terms. (*See id.* at ¶¶ 28 – 33.) He uses this estimate – along with other factors, such as the two companies' profit projections and their expectations regarding the pending patent litigation – to predict what the generic entry date would have been in a no-payment settlement. (*See id.*) Finally, Professor Elhauge considers how sensitive his analysis is to changes in the estimates of each parties' strengths (*e.g.*, patent strength, litigation costs, litigation end date, etc.). (*See id.* at ¶¶ 33 – 54.) He concludes that his finding – that the reverse payment caused a significant delay in entry of generic memantine hydrochloride into the market – is robust enough to hold true even given changes to these estimates. Finally, he posits that Defendants' risk aversion could not have justified the reverse payment. (*See id.* at ¶¶ 56 – 58.)

C. Analysis: Motion to Exclude Professor Elhauge's Reports

Defendants move to exclude the reports and testimony of Professor Elhauge's on three grounds.

First, Defendants argue that Professor Elhauge's opinions are at odds with the Supreme Court's decision in *F.T.C. v. Actavis, Inc.*, 570 U.S. 136 (2013), because Professor Elhauge presumes that *any* payment from a patentee to a prospective generic, regardless of its size or the

reasons for making it, causes anticompetitive delay. That, however, is a mischaracterization of Professor Elhauge's analysis.

The Supreme Court in *Actavis* specifically declined to hold that "reverse payment settlement agreements are presumptively unlawful." *Actavis*, 570 U.S. at 158. It instructed courts reviewing such agreements to proceed by applying a "rule of reason" analysis to reverse payment agreements. *Id.* at 159. Under this analysis, courts have to assess the payment's "size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification." *Id.* at 159. Thus, only those reverse payments that are "'large and unjustified'" violate the antitrust laws. *Sergeants Benevolent Ass'n Health & Welfare Fund v. Acta Vis, PLC*, No. 15 Civ. 6549 (CM), 2016 WL 4992690, at *13 (S.D.N.Y. Sept. 13, 2016) (quoting *Actavis*, 570 U.S. at 158).

As an initial matter, Professor Elhauge explains in his report that "a reverse payment is large enough to anticompetitively delay entry whenever the payment amount exceeds the litigation costs the patent holder avoided by settling." (Elhauge Rep. ¶ 42.) He determines that the reverse payment from Forest to Mylan, which he estimates to be $30.9 million, was large enough to exceed Forest's avoided litigation costs (an estimated $3.5 million) and was thus potentially anticompetitive. (*Id.* at ¶ 11, 20.) Only after determining that the payment exceeded avoided litigation costs did Professor Elhauge proceed to use economic analysis to assess the degree of delay the reverse payment caused. This approach is fully consistent with *Actavis*.

Next, Defendants argue that Professor Elhauge's opinions are speculative, internally inconsistent, and contradicted by the evidence. The Court will not waste time on this, except to say that this part of their *Daubert* motion, "like so many such motions, is nothing more than a 'we do not agree with his opinion so it is junk science' motion, of the sort that causes this and

many judges to view all *Daubert* motions with a certain degree of skepticism." *Bank of New York Mellon Tr. Co., Nat'l Ass'n for Registered Certificate Holders of Morgan Stanley Capital I Inc. v. Morgan Stanley Mortg. Capital, Inc.*, No. 11 Civ. 505 (CM), 2017 WL 733225, at *1 (S.D.N.Y. Feb. 10, 2017). Here, Defendants' disagreements with Plaintiffs' expert are appropriate subjects for cross-examination.

Lastly, Defendants argue that Professor Elhauge's opinions about when entry "would have" occurred improperly attempt to usurp the role of the jury. Defendants cite *to United Food and Commercial Workers Local 1776 & Participating Employers Health and Welfare Fund v. Teikoku Pharma USA*, 296 F. Supp. 3d 1142, 1149 (N.D. Cal. 2017) (hereinafter "*Lidoderm*"), in support. In that case, which also involved an alleged reverse payment settlement, Professor Elhauge similarly opined in support of plaintiffs' alternate causation theory that in the hypothetical but-for world, even without a reverse payment, the defendants would have agreed to a settlement allowing a competitor into the market a year earlier than they did. The defendants in *Lidoderm* moved to exclude Professor Elhauge's economic model and but-for conclusions as unsound, difficult to understand, and not transparent. The court granted the motion in part, holding that "Elhauge may opine that in his view the parties would have been rationally motivated to agree to settlement allowing [a competitor] early entry by specific dates." *Id.* at 1149. The court then held that Elhauge could not "testify that the parties would have agreed to entry on a date certain, as that impinges on a determination left up to the jury." *Id.* So too here.

Professor Elhauge must qualify his opinions by testifying that "it would have been economically rational for both parties" to enter into a no-payment settlement in a but-for world by specific dates, not that they necessarily *would have*. (Opper Decl. Ex. 2, Dkt. No. 421 ("Elhauge Dep. Tr. II") at 225:18-227:18.) That ultimate issue is for the trier of fact to decide.

With that modification, Defendants' motion is DENIED.

3. Dr. Russell Lamb

Defendants move to exclude the opinions and testimony of Plaintiffs' expert, Dr. Russell Lamb, who opines on class certification and damages caused by Defendants' alleged anticompetitive conduct.

Plaintiffs offer Amended Expert Report of Dr. Russell Lamb dated September 20, 2017 (Hamburger Decl. Ex. 2, Dkt. No. 438 (("Lamb Rep.")); and an Amended Expert Reply Report dated November 9, 2017 (*Id.* at Ex. 3 ("Lamb Reply Rep.")) to correct for an error in his earlier reply report.

Dr. Lamb, an economist, was asked to analyze (1) whether the delay in generic entry impacted prices paid by proposed class members; (2) whether Defendants' allegedly unlawful hard switch impacted prices paid by proposed class members; (3) whether it is possible to establish, using economic analyses and evidence common to the proposed class as a whole, rather than specific to individual members, that proposed class members were injured by Defendants' alleged anticompetitive conduct under two separate but-for worlds (as described below); and (4) the amount of aggregate damages suffered by proposed class members as a result of the alleged misconduct under the two separate but-for worlds. (*See* Lamb Rep. ¶ 5.)

For the purposes of his report, Dr. Lamb conducted economic research on the market and prices paid for memantine hydrochloride by members of the proposed class and reviewed transaction-level data produced by Forest and several generic manufacturers. He also reviewed documents produced by various parties in this matter (including documents, expert reports and testimony from the previous action brought by the New York Attorney General), documents or

filings presented before the FDA, as well as a variety of publicly-available documents including trade press and academic literature. (*Id.* at ¶ 12.)

A. Qualifications

Dr. Lamb, an expert in antitrust economics, has testified in U.S. district court on matters concerning antitrust liability, impact, and damages. For more than 20 years, Dr. Lamb has consulted on the economics of markets and prices. (*Id.* at ¶ 2.) Courts have relied upon his economic analyses of the market in certifying classes of direct purchasers and indirect purchasers in litigations involving allegations of anticompetitive conduct. (*Id.* at ¶ 3.) Additionally, he has been hired as an economic consultant to the World Bank and the Government of Peru, and has assisted on various economic consulting projects for private firms, government agencies, and law firms. (*Id.*)

He is the President of an economic consulting firm known as Monument Economics Group, based in Arlington, Virginia. The firm provides economic research and quantitative and statistical analysis to clients in the United States, Canada, and elsewhere internationally. (*Id.* at ¶ 1.) He also currently teaches "Law and Economics" at The George Washington University. (*Id.*)

B. Summary of Dr. Russell Lamb's Reports

Dr. Lamb's reports describe, in part, the relevant pharmaceutical regulatory framework, competitive effects of generic entry, background on the memantine hydrochloride market, and an analysis of the proposed class members. He emphasizes that "By September 2015, three months after generic entry, Forest had lost 89.9 [%] of Namenda IR sales to generic manufacturers" who were selling the drug at about a 95% price discount. (Lamb Rep. ¶ 81 – 82.) He notes that the "rapid substitution of generic memantine hydrochloride for branded Namenda IR, is consistent

with the literature describing the effects of generic entry on prices and sales in pharmaceutical markets." (*Id.* at ¶ 83.)

By way of example, Dr. Lamb suggests that, as a result, proposed class members "who purchased Namenda IR at a price of $0.58 per tablet in July 2015, would have purchased the generic at a price below $0.58 in July 2015 had generic competition started in 2012, rather than July 2015, because had generic competition started in 2012, the decline in generic prices that actually occurred after July 2015 would have occurred much earlier." (*Id.* at ¶ 85.)

Dr. Lamb analyzes "two but-for scenarios that Plaintiffs allege would have occurred in a world free of the Defendants' alleged misconduct" – a No Reverse Payment But-For World and a No Hard Switch But-For World. (Lamb Rep. ¶ 7.)

No Reverse Payment But-For World. Under the first scenario, Dr. Lamb considers damages arising from Forest's alleged reverse payment to Mylan (the "No Reverse Payment But-For World"). He assumes that had "Defendants not entered into an allegedly illegal agreement with Mylan, they still would have settled, but without a large reverse payment and with an entry date [in 2012[1]] (rather than in 2015 as provided for in their . . . agreement)." (*Id.* at ¶ 8.) Using an economic model, Dr. Lamb compares the actual price purchasers paid for memantine hydrochloride to the prices that would have prevailed but for Defendants' conduct, and compares the actual volumes of brand Namenda purchased to the volumes of Namenda that would have been purchased but for Defendants' conduct. (*Id.* at ¶ 127 – 42.)

[1] For the purposes of calculating damages under this scenario, Dr. Lamb relies on an analysis conducted by Professor Einer Elhauge in which he determines that a payment-free settlement would have provided for an entry date of November 2, 2012. Dr. Lamb alternatively assumes a June 2012 generic entry date based on George Johnston's alternative theory that absent a settlement agreement, Mylan would have prevailed in the patent litigation brought against it, resulting in generic entry by it in June 2012, and by other generic competitors under the terms of their agreements with Forest.

He concludes that "all or nearly all proposed [c]lass members were impacted by Defendants' allegedly anticompetitive agreement with Mylan, assuming that generic entry was delayed and would have occurred earlier otherwise, in that they paid higher prices for brand-name Namenda IR, Namenda XR, and/or generic memantine hydrochloride than they otherwise would have had generic competition started sooner, because they would have purchased (or purchased more) generic memantine hydrochloride at prices below branded Namenda and would have purchased the generic at lower prices." (*Id.* at ¶ 13(a).)

No Hard Switch But-For World. Under the second scenario, Dr. Lamb considers damages suffered by direct purchasers of Namenda products arising solely from Forest's announcement of a hard switch from Namenda IR to Namenda XR (the "No Hard Switch But-For World"). To confirm his hypothesis that Forest's February 2014 discontinuation announcement had an impact on the market, Dr. Lamb conducted a statistical analysis called a "structural break test" to analyze conversion to Namenda XR using market share data from NSP. (*See id.* at ¶ 119.) He concludes that "there is a structural break in the Namenda XR conversion rate at the time the Hard Switch strategy was implemented beginning in February 2014," (*id.*), which illustrates that the hard switch was effective in converting more Namenda IR prescriptions to Namenda XR than otherwise would have been the case. He goes on to analyze the case in which Defendants did not engage in their hard switch strategy (never announced that they would remove Namenda IR from the market) and no generic entry occurred prior to the actual date at which AB-rated generics for Namenda IR became available (*i.e.*, July 2015).

He concludes that "all or nearly all proposed [c]lass members who purchased at least Namenda IR and XR, or XR, were impacted by Defendants' anticompetitive [h]ard [s]witch strategy in that they paid higher prices for Namenda XR than they otherwise would have for

generic memantine hydrochloride, and they would have purchased the less expensive generic (or more of it) in place of the more expensive branded Namenda." (*Id.* at ¶ 13(b).)

For purposes of class certification, Dr. Lamb finds that aggregate overcharge damages can be proven through classwide economic models using formulas and methodologies that do not require individualized analysis. (*Id.* at ¶ 121 – 61.) Where available, he uses transaction-level data produced by Forest and some of the generic manufacturers to calculate damages. He calculates the "aggregate, class-wide damages arising from Defendants' alleged misconduct under the two separate but-for worlds." (*Id.* at ¶ 13.) He estimates that "Total damages suffered by Proposed Class members are between $6.09 billion and $6.93 billion under the No-Reverse Payment But-For World, and between $776 million and $814 million under the No Hard Switch But-For World." (*Id.*)

C. Analysis: Motion to Exclude Dr. Lamb's Reports

An antitrust claim has three elements: (1) a violation of antitrust law; (2) injury and causation; and (3) damages. *In re Visa Check/MasterMoney Antitrust Litig.*, 280 F.3d 124, 136 (2d Cir. 2001). This portion of Defendants' motion centers on proof of the second element of an antitrust claim – commonly referred to as "antitrust injury" – which requires "an antitrust plaintiff [to] prove that its injury was, in fact, caused by the defendant's violation of the antitrust laws." *US Airways, Inc. v. Sabre Holdings Corp.*, No. 11 Civ. 2725 (LGS), 2017 WL 1064709, at *16 (S.D.N.Y. Mar. 21, 2017) (quoting *U.S. Football League v. NFL*, 842 F.2d 1335, 1377 (2d Cir. 1988)).

Defendants move to exclude the reports and testimony of Dr. Lamb on three grounds.

First, Defendants argue that Dr. Lamb's structural break test does not prove antitrust injury. Defendants claim that Dr. Lamb's test fails because it utilizes market-wide data rather

than purchaser-specific information, which approach fails to isolate and measure those patients who switched from Namenda IR to XR *because of the February 2014 announcement* from those patients who switched for other reasons. Stated otherwise, Defendants claim that Dr. Lamb's analysis understates the degree to which Namenda XR could have captured the market even without the hard switch strategy.

This argument is unpersuasive.

Dr. Lamb's conclusion that the hard switch announcement increased conversion to Namenda XR was based on a number of observations that are consistent with Plaintiffs' allegations. Plaintiffs allege "that as a result of Forest's dissatisfaction with the extent of conversion to Namenda XR for several months after its launch, Forest began to consider an option where it would discontinue or dramatically restrict the supply of Namenda IR several months before the availability of generic memantine hydrochloride in order to accomplish a 'forced switch' whereby physicians and patients would have little choice but to switch to Namenda XR." (*Id.* at ¶ 89.) In support of this theory, Dr. Lamb reviewed Forest's internal documents and forecasts confirming the company's formation and implementation of their strategy to reduce the level of competition from generic memantine hydrochloride products. (*See id.* at ¶ 95.) Dr. Lamb relied on forecasts that contained both a "withdrawal" (or "hard switch") scenario and a "conventional" (or "soft switch") scenario, as well as internal high-level discussions of and reliance upon these forecasts to reach conclusions about what the conversion rate of Namenda IR to XR would have been absent initiation of the hard switch strategy. For example, Figure 6 entitled *Forest Namenda Forecasts*, is a copy of Forest's soft switch and hard switch projections which show that Namenda XR's share of the memantine hydrochloride

market would be significantly higher under the hard switch strategy versus the soft switch strategy. (*Id.*) Dr. Lamb also notes that:

> In a May 2013 speech concerning the launch of Namenda XR, Mark Devlin of Forest stated: '[T]he core of our brand strategy with XR is to convert our existing IR business to Namenda XR as fast as we can and also gain new starts for Namenda XR. We need to transition volume to XR to protect our Namenda revenue from generic penetration in 2015 when we lose IR patent exclusivity.' Mr. Devlin added that the 'better job we do moving business form IR to XR, the more Forest revenue we hopefully shelter from generic threats down the road.'

(Id. at ¶ 94.)

Furthermore, the evidence includes sworn statements from doctors stating that they stopped prescribing Namenda IR after the hard switch announcement. (*See id.* at ¶ 104.) Dr. Lamb concludes that the evidence demonstrates that Forest's intention to withdraw Namenda IR was to trigger wide-spread conversion to Namenda XR and that the February announcement was successful in starting to do so.

To confirm his hypothesis, Dr. Lamb conducted a regression analysis called a "structural break test" showing that Forest's implementation of its hard switch strategy would impact the market by increasing conversion to Namenda XR. He used actual sales data from IMS National Sales Perspectives ("NSP"). He concludes that "there is a structural break in the Namenda XR conversion rate at the time the Hard Switch strategy was implemented beginning in February 2014," (*id.* at ¶ 119), which illustrates that the hard switch was effective in converting more Namenda IR prescriptions to Namenda XR than otherwise would have been the case.

Defendants' complain that Dr. Lamb's structural break test fails because it does not isolate the cause of the February 2014 break. However, Dr. Lamb testified that the test was not designed to do so. He testified that "[the test] is not able to tease out where the source of the structural break comes from by itself. One has to implement it because one believes that there is

some event which leads to a structural break. . . I had reason to believe that the hard switch strategy which began somewhat before February '14 and which included the announcement . . . would have an effect at that point. And that's why I chose that date." (Hamburger Decl. Ex. 19, Dkt. No. 438 ("Lamb Dep. Tr. I") at 96:2 – 19.)

In other words, Dr. Lamb's test demonstrates that there was a "structural break" in February 2014, which happened to be the date when the hard switch was announced. Correlation does not prove causation, but the coincidence in timing between the announcement and the structural break shown by the data is some evidence of causation in support of Plaintiffs' theory. Perhaps other things were happening in the market in February 2014, and Forest may go into them to undercut Dr. Lamb's data. Taken together with the other evidence analyzed by Dr. Lamb, the regression is designed to confirm a hypothesis that is itself based on other indicia. For the purposes of *Daubert*, Dr. Lamb's analysis passes muster. "At most, [Forest's] arguments concerning the assumptions in [Dr. Lamb's] analysis go to its weight, not admissibility of that testimony." *Dial Corp. v. News Corp.*, No. 13 Civ. 6802, 2016 WL 690868, at *4 (S.D.N.Y. Feb. 17, 2016).

Moreover, contrary to Defendants' argument, a plaintiff is only required to show that alleged illegal conduct is "*a* material cause of the [antitrust] injury; a plaintiff need not exhaust all possible alternative sources of injury in fulfilling his burden of proving compensable injury." *Id.* (quoting *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 114 n.9 (1969)) (emphasis added). "[T]o prove a 'causal connection' between the defendant's unlawful conduct and the plaintiff's injury, the plaintiff need only 'demonstrate that [the defendant's] conduct was a substantial or materially contributing factor' in producing that injury." *In re Publ'n Paper Antitrust Litig.*, 690 F.3d 51, 66 (2d Cir. 2012) (quoting *Litton Sys., Inc. v. AT & T Co.*, 700 F.2d

785, 823 n.49 (2d Cir. 1983)). Second Circuit precedent makes clear that in order to prove causation:

> [P]laintiffs do not have to prove that the unlawful activity that the defendants allegedly engaged in was the sole cause of their injuries. Plaintiffs meet their burden if they show that the defendants' unlawful facts substantially contributed to their injuries, even though other facts may have contributed significantly. An antitrust plaintiff is not required to show that the defendants' acts were a greater cause of the injury than other factors. Plaintiffs need only show that their injury to *some* degree resulted from defendants' violation.

NFL, 842 F.2d at 1377 (emphasis in original).

Second, Defendants argue that Dr. Lamb improperly expanded the time period of alleged injury to include data from before the February 2014 Namenda IR discontinuation announcement and after the injunction on Namenda XR conversion.

Specifically, Defendants claim that his methodology improperly includes alleged injury from before the February 2014 announcement, in violation of this Court's earlier conclusion about the proper damages period. *See Sergeants Benevolent Ass'n Health & Welfare Fund v. Actavis, PLC*, Nos. 15 Civ. 6549, 15 Civ. 7488, 2016 WL 4992690, at *11 (S.D.N.Y. Sept. 13, 2016) ("According to the Second Circuit: The hard switch began on February 14, 2014 with the announcement of Defendants' intention to withdraw Namenda IR and was suspended in September 2014 when Defendants agreed to a "standstill" during the litigation proceedings.") (internal citation omitted).) In his report, Dr. Lamb cites documents demonstrating that, before the February 2014 announcement, Forest had already begun discussed its hard switch plan outside the company. (*See* Lamb Rep. ¶¶ 89, 102.)

Plaintiffs argue that Dr. Lamb included discussion of pre-February 2014 conduct in order to undercut Forest's theory – that increased conversion to Namenda XR after February 2014 was the result of better formulary placement for XR rather than the hard switch. (Lamb Reply Rep. ¶

51; *see also* Lamb Rep. ¶¶ 89, 102; Berndt Rep. ¶ 56; Berndt Reply Rep. ¶ 29; PRSoF ¶ 373; PASoF ¶ 67 (collecting evidence of Forest's leveraging of withdrawal plan to achieve better formulary placement).) These opinions are admissible. Defendants' difference of opinion is fair ground for cross examination. Likewise are Dr. Lamb's opinions about any lasting impact the anticompetitive conduct had post-injunction.

Lastly, Defendants argue that the flaws in Dr. Lamb's "No Hard Switch" methodology make his No Reverse Payment methodology unreliable as well. For the reasons discussed above, this argument is without merit.

Defendants' motion is DENIED.

4. Forecast Averages from Dr. Russell Lamb and Dr. Ernst Berndt

Defendants move to exclude the opinions and testimony of Plaintiffs' experts, Dr. Russell Lamb and Dr. Ernst Berndt, regarding their use of forecast averages in their respective analyses. This motion is DENIED.

Dr. Berndt, a Professor in Applied Economics at the Sloan School of Management at the Massachusetts Institute of Technology, submitted: (1) an initial report dated September 15, 2017 (Hamburger Decl. Ex. 7, Dkt. No. 438 ("Berndt Rep.")); (2) a reply expert report dated October 25, 2017 (*Id.* at Ex. 8 ("Berndt Reply Rep.")); and an amended reply expert report dated November 8, 2017 (*Id.* at Ex. 9 ("Berndt Am. Reply. Rep.")).[2] In his initial report, Dr. Berndt opines on (1) "whether it is reasonable as a matter of economics to conduct a damages analysis of the impact of Forest's announcement and conduct of a 'hard switch' marketing campaign . . .

[2] Defendants ask the Court to strike Dr. Berndt's Amended Reply Report as an improper sur-rebuttal based on Dr. Berndt's treatment of issues and documents raised during his deposition about his initial report. The Court will do no such thing. *See Cedar Petrochemicals, Inc. v. Dongbu Hannon Chem. Co.*, 769 F. Supp. 2d 269, 277 – 79 (S.D.N.Y. 2011). Defendants are not unduly prejudiced by Dr. Berndt's review and informed response to their challenges raised at deposition.

based upon use of relevant Forest projections and forecasts" and if so, (2) "what objectively reasonable expected market share Namenda XR would have had if there had been no Hard Switch announcement and marketing campaign (as shown by Forest's reasonable forecasts)." (*See* Berndt Rep. ¶ 6.)

In his report, Dr. Lamb relies on Dr. Berndt's "opinion that these forecasts of the Namenda XR conversion rate are a reliable basis for an analysis of the incremental effect of the Hard Switch on the conversion from branded Namenda IR to branded Namenda XR." (Lamb Rep. ¶ 144.) Thus, Dr. Lamb factored Forest's forecasts into his damages analysis. Specifically, based on Forest's predictions of Namenda XR conversion absent the hard switch, he concluded that the "Namenda XR conversion rate would rate 30 percent in 18 months after Namenda XR entered the market absent the Hard Switch." (*Id.* at ¶ 150.) For purposes of his damages calculation, "The difference between the actual and but for Namenda XR conversion rates, multiplied by total market DOT [days of therapy] times the generic penetration rate, yields the amount of branded XR purchases that would have been generic Namenda IR purchases but for the Hard Switch. This volume multiplied by the difference in price between branded Namenda XR and generic Namenda IR then yields the amount of overcharges to the Hard Switch." (*Id.* at ¶ 13.)

A. Analysis: Motion to Exclude Dr. Berndt's and Dr. Lamb's Forecast Averages

Defendants' principal complaint is that the experts blindly adopt certain of Forest's forecasts without first scrutinizing them. However, a substantial portion of Dr. Lamb's report and the entirety of Dr. Berndt's report are dedicated to analyzing and evaluating Forest's forecasts for reliability. That hardly renders their conclusions inadmissible.

Defendants advance three reasons why this testimony should not be admitted.

First, Defendants argue that Dr. Berndt and Dr. Lamb did not perform any economic analysis to determine what the conversion rate would have been in the but-for world.

Second, Defendants argue that neither of the doctors applied any expert methodology to average forecasts or to select which forecasts to include in their averages, and that as a result both doctors haphazardly selected forecasts for their averages.

Third, Defendants argue that neither doctor tested the forecasts to determine their reliability.

None of these arguments holds water.

In his report, Dr. Berndt undertook a robust analysis of the process by which Forest came to its forecasts and expectations for the conversion rate between Namenda IR and Namenda XR under a soft switch and a hard switch scenario. He closely studied the inputs into Forest's analysis, analyzed the evolution over time of that analysis, and Forest's internal and external use and reliance upon that analysis. In particular, Dr. Berndt considered that Forest had been in the market for many years, was very familiar with the dynamics between physicians, caregivers, patients, and the various health care entities involved in the treatment of Alzheimer's patients. (Berndt Rep. ¶ 40.)

Dr. Berndt considered that Forest had done a searching analysis of analogous situations in which pharmaceutical manufacturers had brought an extended release product into a market in which that company already had an immediate release product. (*Id.* at ¶ 41.)

Dr. Berndt considered that Forest surveyed physicians, caregivers, pharmacists and health care entities about the Namenda XR launch and conversion. (*Id.* at ¶ 26.)

Dr. Berndt considered that Forest specifically factored in the impact of a cost-conscious and critical segment of the market for Namenda Alzheimer's patients, Long Term Care. (*Id.* at ¶

28.) Dr. Berndt considered that Forest's analysis evolved over time, including with the assistance of actual sales data after Namenda XR launched. (*Id.* at ¶ 51– 55.)

Dr. Berndt also considered that Forest's executives valued these analyses as reliable and accurate as they used them when communicating their expectations about Namenda XR share in the soft switch scenario internally (including to Forest's Board of Directors) and externally to the investing community. (*Id.* at ¶ 32 – 38, 48 – 50.)

Thus, Dr. Berndt did not just assume, as Defendants argue, that Forest's estimates of a 30% conversion in a "soft switch" scenario were reliable (as found by Judge Sweet and adopted for purposes of the motion to dismiss by me). (*See* Dkt. No. 253 at 24 – 25 (citing *New York v. Actavis, PLC (Namenda I)*, No. 14 Civ. 7473, 2014 WL 7015198, at *80, 109 – 11 (S.D.N.Y. Dec. 11, 2014)). Instead, Dr. Berndt applied his scholarship, knowledge, and experience from his many decades of studying the pharmaceutical industry. He analyzed the work that Forest put into its forecasting, as well as the extent to which Forest relied upon those forecasts in making business decisions and communicating with the investor community. He endeavored to determine that the forecasting effort was robust and reliable.

Dr. Berndt concludes that "the [internal] forecasts reviewed by Dr. Lamb [were] reliable," as they were based on Forest's own study of the Namenda market and analogous experiences of other drugs. (*Id.* at ¶ 40; *see also* Berndt Reply Rep. ¶¶ 4 – 20.) He further concludes that "[t]he appropriate 'but for' analysis in this case is one in which Forest makes no hard switch announcement of any kind, executes no communications campaign of any kind aimed at alerting patients . . . and others of the impending withdrawal of Namenda IR, and makes no other effort of any kind to implement the hard switch." (Berndt Rep. ¶ 69.)

Likewise, Dr. Lamb independently reviewed and analyzed Forest's internal document and testimony regarding the soft-switch conversion rate. He did not blindly adopt Dr. Berndt's analysis. He factored in the fact that, "Forest used various analogues of drug franchises that had experienced conversion from an immediate release to an extended release product when forecasting the conversion rate from Namenda IR to XR." (*Id.* at ¶ 151.) He noted that Forest updated the Namenda XR conversion forecasts regularly, sometimes creating multiple forecasts in a few weeks. (*See id.*) Using the forecast documents that were created after Namenda XR had entered the market and before the hard switch was implemented, Dr. Lamb averaged the forecasted soft switch Namenda IR to XR conversion rate for November 2014, 18 months after Namenda XR entered the market, and found the but-for conversion rate to be approximately 30 percent. (*Id.* at ¶ 152; *see also id.* at Tbl. 3.) Contrary to Defendants' argument, Dr. Lamb did not "cherry-pick." He averaged multiple iterations of Forest's forecasts and came up with a 30% conversion rate. He then confirmed this number was reasonable based on its specific use in numerous company presentations, statements by company executives on earnings calls, and testimony by these executives. (*See id.* at ¶ 154.)

The use of Defendants' own forecasts to model a but-for world has been held to be a sound economic methodology. Indeed, it is commonly used in courts considering generic delay damages. *See, e.g.*, *King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, 309 F.R.D. 195, 212 (E.D. Pa. 2015), *rev'd and remanded on other grounds, In re Modafinil Antitrust Litig.*, 837 F.3d 238 (3d Cir. 2016). Defendants may not hide behind the fact that forecasts are predictions, and by their very nature incorporate some uncertainty – particularly given the controlling legal rule that a defendant may not benefit from any uncertainty concerning damages its own wrongful conduct has caused.

Defendants' complaint that Drs. Berndt and Lamb did not consider all forecasts from the relevant period before the hard switch conduct is of no moment to the admissibility of their testimony. This is a matter for cross-examination. If Forest contends that important forecasts were omitted from the experts' analysis, it can introduce them at trial.

The motion is DENIED.

5. Professor John R. Thomas, Esq.

Defendants move to exclude the opinions and testimony of Plaintiffs' expert, Professor John R. Thomas, Esq. Plaintiffs substituted Professor Thomas in place of their proposed expert, Deborah Jaskot, after this Court granted Teva Pharmaceutical USA, Inc.'s nonparty motion to disqualify Ms. Jaskot from serving as Plaintiffs' regulatory expert due to her conflicts as a former Teva executive. (*See* Dkt. No. 355.)

Plaintiffs offer a report from Professor Thomas dated November 14, 2017 (Johnson Decl. Ex. 1, Dkt. No. 506 (Expert Report of Professor John R. Thomas, Esq. ("Thomas Rep.")).) Plaintiffs retained Professor Thomas to (1) provide testimony concerning the Drug Price Competition and Patent Term Restoration Act (the "Hatch-Waxman Act"), Pub. L. No. 98-417, 98 Stat. 1585, "and its 'grand bargain' between the competing interests of promoting the innovation of new drugs and promoting competition from generic drugs;" (2) "determine whether there would be any impediments to certain generic drug companies obtaining final approval from [the] FDA to sell their generic versions of Namenda at any point from April 17, 2011 through July 11, 2015;" and (3) "determine whether there would have been any impediments to Forest obtaining approval from [the] FDA to market an authorized generic version of Namenda from April 17, 2011 through July 11, 2015." (Thomas Rep. ¶¶ 3 – 5.)

A. Qualifications

Professor Thomas has taught courses on the Hatch-Waxman Act at Georgetown Law School since 2002, has written a textbook concerning the Hatch-Waxman Act, patent law, and pharmaceutical drugs, and has been qualified to opine on ANDAs in district court before. *See, e.g., Apotex, Inc. v. Cephalon, Inc.*, 06 Civ. 02768, 2011 U.S. Dist. LEXIS 154863 (E.D. Pa. Mar. 28, 2011). He possesses more than two decades of experience with respect to the Hatch-Waxman Act, including authoring and co-authoring numerous Congressional Research Service Reports. He was appointed and served as a Special Master in Hatch-Waxman litigation. (*Id.* at ¶ 15.)

He has taught hundreds of patent examiners principles of patent and evidence law as an instructor at the U.S. Patent and Trademark Office Patent Academy, and is admitted to both the patent bar (No. 40,389) and the bar of the state of Maryland. (*Id.* at ¶¶ 11 – 13.) Moreover, he has practiced patent law full-time as an associate attorney at Finnegan, Henderson, Farabow, Garrett & Dunner LLP in Washington, D.C. (*Id.* at ¶ 13.)

B. Summary of Professor John R. Thomas, Esq.'s Report

Professor Thomas divides his analysis into three sections.

First, he discusses the relevant regulatory background regarding drug approval under the Hatch-Waxman Act, including the FDA approval process for brand name and generic drugs generally, the FDA's orange book listing of approved drug products, along with the various marketing exclusivities made available by the Act.

Second, Professor Thomas gives background on the FDA approval of branded and generic Namenda, including the various generic challenges to Forest's Namenda patent, Forest's settlement of these challenges, and the generics' respective approval and launch timelines.

Third, Professor Thomas opines that based on his analysis of the available data, there were no regulatory impediments to the five generics seeking and obtaining final approval for their generic versions of Namenda on or after April 17, 2011.

C. Analysis: Motion to Exclude Professor John R. Thomas, Esq.'s Reports

Defendants move to exclude the reports and testimony of Professor Thomas on three grounds.

First, Defendants call certain portions of Professor Thomas's opinion irrelevant and prejudicial. For example, the professor writes, "When competitors within the pharmaceutical industry . . . choose to bypass or subvert the legislative framework, they potentially engage in strategic behavior that defies the policy goals embodied in the Hatch-Waxman Act." (Thomas Rep. ¶ 30.) They argue that Professor Thomas implies that *all* Hatch-Waxman patent settlements are "suspect" or "inherently 'subvert' Congressional intent to make low-cost generic pharmaceuticals broadly available to the public." (Defs.' Mem. of Law at 1.) This argument lacks even a scintilla of merit. Defendants cannot point to a single instance where Professor Thomas actually offers such an opinion. As for what Defendants believe he "implied," their beliefs are of no moment. This basis for the motion to exclude is DENIED.

Second, Defendants argue that Professor Thomas should not be allowed to explain the Hatch-Waxman statutory scheme, its regulations, and how they relate to the generics and potential authorized generics in this case. According to Defendants, those explanations would constitute improper legal opinions. They are wrong.

While, "This circuit is in accord with other circuits in requiring exclusion of expert testimony that expresses a legal conclusion," *Hygh v. Jacobs*, 961 F.2d 359, 363 (2d Cir. 1992), "expert testimony is viewed as helpful in cases, like this one, involving complex statutes or issues

outside of the general knowledge of the jury." *United States v. Universal Rehab. Servs., Inc.*, No. 94 Cr. 147, 1996 WL 297575, at *10 (E.D. Pa. May 31, 1996), *aff'd sub nom. United States v. Universal Rehab. Servs. (PA), Inc.*, 205 F.3d 657 (3d Cir. 2000). In his report, Professor Thomas explains the procedures under the complex law governing approvals of generic drugs, which is subject matter that is foreign to the average person. He does not provide "legal conclusions" or opine on whether Defendants violated the Act, but simply explains the mechanics of drug approval, which provides context that is likely to "assist the trier of fact." Fed. R. Evid. 702. I will not preclude this testimony. If Thomas's testimony strays beyond that into matters that are irrelevant or otherwise inadmissible, I will be the first to disallow it.

Finally, Defendants claim that Professor Thomas is not qualified to opine on Abbreviated New Drug Application ("ANDA") approval, since he has neither personally prepared nor filed an ANDA, has never communicated with the FDA regarding an ANDA, and has never worked within the FDA or any pharmaceutical company. That all may be true, but it is of no moment. Professor Thomas has taught courses on the Hatch-Waxman Act at Georgetown Law School since 2002, has written a textbook concerning the Hatch-Waxman Act, patent law, and pharmaceutical drugs, and has been qualified to opine on ANDAs in district court before. *See, e.g.*, *Apotex*, 2011 U.S. Dist. LEXIS 154863. Defendants are free to argue to the jury that Dr. Thomas' lack of practical experience undermines his conclusions; the jury can evaluate that argument for what it is worth. I personally would find it unpersuasive.

6. George W. Johnston

Defendants move to exclude the opinions and testimony of Plaintiffs' expert, George W. Johnston, Esq.

Plaintiffs offer a report from George W. Johnston, Esq., dated September 15, 2017 (Hamburger Decl. Ex. 12, Dkt. No. 438 ("Johnston Rep.").) Plaintiffs retained Mr. Johnston to assess what a reasonable and competent patent attorney would have advised the litigants at the time they settled the Namenda patent litigation in terms of 1) their likelihood of success in the litigation; 2) each of the parties' likely litigation costs; and 3) the likely litigation timing, if the parties had not settled, but rather had continued to litigate through a final, non-appealable judgment. (*See* Johnston Rep. ¶ 15.)

A. Qualifications

Mr. Johnston has spent his entire legal practice as a patent attorney, has over 40 years of experience, and has prosecuted hundreds of patent applications before the United States Patent and Trademark Office ("USPTO"). His experience with patents includes evaluating the patentability of inventions, the scope of patent claims, the validity and enforceability of patents, and the infringement of patents. (*Id.* at ¶ 2.)

He served for 17 years as Chief Patent Counsel for Hoffmann-La Roche Inc. ("Roche") – a global pharmaceutical, biotechnology, and diagnostic health care organization. (*Id.* at ¶¶ 3, 6.) During his tenure at Roche, Mr. Johnston "advise[d] senior management on the likelihood that Roche would prevail in potential and actual patent litigations, the cost of the associated litigations, and the possible timing and duration of the litigations." (*Id.* at ¶ 5.)

Mr. Johnston retired from Roche in 2013 as a Vice President and Chief Patent Counsel. (*Id.* at 10.) He continues to practice intellectual property law as Counsel at Gibbons P.C. (*Id.* at ¶ 11.)

Mr. Johnston has impressive credentials as a patent attorney and legal adviser to drug companies. He is certainly an expert in that capacity. The question is whether the opinions he offers in his report go beyond his area of expertise. I conclude that they do not.

B. Summary of George W. Johnston, Esq.'s Report

Mr. Johnston's detailed report begins with a brief description of the patenting process – clarifying that a "U.S. patent provides the patent holder with the right to seek to exclude others from making, using, selling, or importing the invention claimed in the patent for the period during which the patent is in force." (*Id.* at ¶ 19.) He also "discuss[es] the process for extending the term of a pharmaceutical patent under the Hatch-Waxman [and] the procedure under the Hatch-Waxman Act by which a generic manufacturer can challenge pharmaceutical patents listed in the Orange Book so it can enter the market before the patents expire." (*Id.* at ¶ 21.)

Then he provides summarized factual information about the Namenda patent ('703 patent) that would be known to a general counsel who was advising his client whether or not to settle a lawsuit – information about the patent's filing, its alleged inventive concept, and Forest's New Drug Application. (*Id.* at ¶ 26 – 35.) He notes that "The '703 patent relates generally to methods for the treatment or prevention of cerebral ischemia using adamantine derivatives, including memantine and amantadine. [It] recognizes that certain adamantine derivatives, including memantine, were already known and described in the art for the treatment of central nervous system disorders." (*Id.* at ¶ 31.) The '703 patent describes an alleged "new mode" of action of certain adamantine derivatives. As named inventor, Dr. Bormann, explained: "[t]he invented concept is that neurodegeneration is caused by calcium overload of the cells and that you can prevent neurodegeneration by memantine or by adamantine derivatives. That's the invention." (*Id.* at ¶ 32.) This summary of background information sets the stage for his opinion.

Mr. Johnston also recounts the prosecution history of the '703 patent, the USPTO's reexamination of the patent in 2004, and Forest's receipt of Paragraph IV challenges from 15 generic companies in 2007 and 2008. "In their Notice Letters, the Generic Companies argued a variety of defenses including noninfringement and invalidity of the '703 patent under 35 U.S.C. §§ 101, 102, 103, 112, 156, and 305." (*Id.* at ¶ 58.) "In response to the . . . Notice Letters, Forest and Merz instituted a number of Hatch-Waxman litigations in the United States District Court for the District of Delaware and elsewhere." (*Id.* at ¶ 59.) "In their Answers and Counterclaims in the Namenda Litigation, the Generic Companies asserted a number of defenses including: noninfringement; invalidity under 35 U.S.C. §§ 101, 102, 103, 112, 156, and 305; failure to state a claim; lack of subject matter jurisdiction; unclean hands; prosecution history estoppel; inequitable conduct; failure to comply with 35 U.S.C. § 156; patent misuse; equitable intervening rights; as well as counterclaims seeking: declaratory judgment of noninfringement and invalidity; an order to de-list the '703 patent from the Orange Book; and a declaratory judgment of invalidity of the patent term extension of the '703 patent." (*Id.* at ¶ 63.) A patent lawyer advising a client about the probability of success in an infringement lawsuit would of course have studied the file wrapper and become familiar with the patent's prosecution.

He then summarizes the history of all 15 of Forest's '703 patent litigations against the generic companies leading up to and including settlements in 2009-2010. That information is, of course, a matter of public record. He notes that "Mylan's case progressed the farthest," not settling until August 26, 2010.

He then examines other information that a reasonable patent counsel who was evaluating whether or not to settle a case would have taken into account. He explained data that showed the statistical likelihood that either a patentee or a challenger would win a Hatch-Waxman lawsuit –

the actual track record in real litigations. He then evaluated, in the manner that a reasonable and competent patent attorney would, the information that was available to him about the merits of the Namenda litigation between Forest and Mylan. And as part of that analysis, he discussed in depth the legal claims and defenses raised. For example, he evaluates the strength of Mylan's invalidity defenses, including anticipation, obviousness, enablement and patent term extension. In doing so, he brought to bear his extensive knowledge of patent law and patent litigation. He reviews the evidence and expert opinions that Forest and Mylan planned to offer at trial. He analyzes them, and assesses the likelihood that a trier of fact would accept that evidence and those opinions. (*See id.* at ¶¶ 398 – 401.)

In short, he does exactly what he did time and again during his years as Chief Patent Attorney at Hoffman-LaRoche. And his conclusions are summarized in a table on page 94. (*See id.* at ¶ 395.)

After conducting this thorough analysis, he offers the opinion on which Plaintiffs rely: "In my opinion, a reasonable and competent patent attorney at the time of the settlement of the Namenda Litigation likely would have concluded that overall Mylan had greater than a 60% chance of prevailing and that Forest Merz had less than [a] 40% chance of prevailing in this litigation through trial and appeal." (*Id.* at ¶ 16.)

Finally, he estimates the expected length and cost of the Namenda litigation, assuming Mylan and Forest had not settled and the case went to trial.

C. Analysis: Motion to Exclude George W. Johnston, Esq.'s Report

Defendants first argue the Mr. Johnston does not have the technical expertise required to opine on patent infringement and validity, because he is not one skilled in the art covered by the patent – he is a lawyer, not a chemist. They urge that allowing Johnston to offer his opinion would

run counter to the Federal Circuit's holding in *Sundance, Inc. v. Demonte Fabricating Ltd.*, 550 F.3d 1356, 1363 (Fed. Cir. 2008).

Plaintiffs counter that Mr. Johnston is not offering independent technical expertise about whether the claims of the '703 patent were in fact valid or whether they were infringed by Mylan. They argue that he opines, from the perspective of a reasonable patent attorney with extensive experience in the area of patent law, about the likelihood that Mylan would succeed in its lawsuit against Forest. Plaintiffs note that Johnston relies on the conclusions of the parties' technical experts – persons who are "skilled in the art" – in reaching his own conclusions. (*See* Opper Decl. Ex. 8, Dkt. No. 421 ("Johnston Dep.") at 172:23 – 173:6 ("I had a different role than that of a technical expert. I had a very focused role in terms of what a reasonable patent attorney . . . say, a chief patent counsel, because we did it all the time, would have perceived as the likelihood of success at the time of settlement.").) Plaintiffs thus argue that his testimony does not run afoul of *Sundance*.

Sundance was a patent infringement case. In that case the district court had denied Sundance's motion *in limine* to exclude the testimony of an opposing expert, Bliss. Bliss was "a patent attorney with extensive experience in patent law and procedure." *Sundance*, 550 F.3d at 1360. He opined, on behalf of the alleged infringer, that the patent was invalid, and that if it were valid it was not infringed – even though Mr. Bliss had no technical expertise in the field of the patent. *See id.*

The Federal Circuit reversed, concluding that the district court had abused its discretion by admitting Bliss' opinion evidence. The court emphasized that "Mr. Bliss is not qualified to testify as an expert witness on the issues of infringement or validity [as] [t]hese issues are analyzed in great part from the perspective of a *person of ordinary skill in the art*" and Mr. Bliss lacked such

skill. *Id.* at 1361 (emphasis added). In other words, "Unless a patent lawyer is also a qualified technical expert, his testimony *on these kinds of technical issues* is improper and thus inadmissible." *Id.* at 1362 (emphasis added).

"*Sundance* actually advises district courts to consider the perspective from which the relevant issue of patent law will be analyzed when the court determines whether an expert is qualified to testify as an expert on that issue." *Network-1 Techs., Inc. v. Alcatel-Lucent USA, Inc.*, No. 6:11 Civ. 492 (RWS), 2017 WL 4173468, at *3 (E.D. Tex. Sept. 21, 2017) (citing *Aevoe Corp. v. AE Tech Co.*, No. 2:12 Civ. 0053 (GMN), 2014 WL 4182343, at *2 (D. Nev. Aug. 20, 2014)).

This case differs from *Sundance* in two important ways.

First and foremost, this is an antitrust case, not a patent infringement case; the Court's concern with the technical issues of patent infringement and validity is indirect.

Second, Mr. Johnston is not opining that the '703 is invalid, or that Mylan did not infringe the patent. Instead, he offers a "reasonable patent attorney's" assessment of the likelihood that Mylan would win its patent case – exactly the sort of assessment he would have offered his client during the nearly two decades when he served as Chief Patent Counsel of Hoffman-LaRoche.

Nonetheless, it would be naïve to conclude that Mr. Johnston's assessment of Mylan's likelihood of succeeding on its claims in the lawsuit does not include some tangential assessment on his part on the issues of the validity and infringement. True, he does not offer the sort of opinion that one skilled in the art would offer – a black-and-white, yes or no, opinion that the patent was or was not valid or infringed. But Johnson's assessment that Mylan's experts were more likely to be believed that Forest's, and his assignment of statistical likelihoods to those technical opinions necessarily depends on his lawyerly assessment of how the ultimate issues in that patent litigation would play out. His conclusion – that Mylan would more likely than not have managed to prove

either invalidity or lack of infringement – had to rest on some assessment of the patent's validity and Mylan's defenses to Forest's charge of infringement.

That said, testimony by experienced lawyers about the likelihood that patent litigations will succeed or not succeed has been admitted in several post-*Actavis* reverse-payment cases. *See In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, No. CV 14-MD-02503, 2018 WL 563144, at *16 (D. Mass. Jan. 25, 2018); *In re Wellbutrin XL Antitrust Litig.*, 133 F. Supp. 3d 734 (E.D. Pa. 2015), *aff'd sub nom. In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132 (3d Cir. 2017), *judgment entered sub nom. In re Wellbutrin XL Antitrust Litig.*, No. 15-2875, 2017 WL 3529114 (3d Cir. Aug. 9, 2017); *see also In re Lidoderm Antitrust Litigation*, 2017 U.S. Dist. LEXIS 182940, *117 (Nov. 3, 2017 N.D. Cal.). Unfortunately, in none of those opinions does the court analyze the lawyer's credentials in any detail or so much as mention the issue identified by this Court in the preceding paragraph. But in every such case the issue was litigation risk and lawyers, not chemists, normally assess litigation risk for their clients.

Mr. Johnson unquestionably has the expertise to evaluate the things he assessed – from expert reports to patent file folders – and to draw conclusions about who is more likely to win a patent lawsuit. He has done it dozens of times for his employer; there is no reason why he should not be able to do it for Plaintiffs in this lawsuit. To the extent that his opinions rest on his evaluation of technical material – the opinions of the technical experts – he can be cross-examined about his knowledge of the underlying art, or the lack of the same. And of course Forest is offering the testimony of its own expert (*see* Hamburger Decl. Ex. 13, Dkt. No. 438 (Expert Report of Roderick McKelvie, Esq. ("McKelvie Rep."))) who will be testifying about his assessment of the merit or lack of merit to the Mylan patent case – the assessment that was actually made before the case settled.

As Judge Casper noted when she admitted "Johnston-like" expert testimony in *In re Solodyn*, "To the extent Defendants seek to challenge [an expert's] conclusions as to the likely outcome of the patent challenges, they may do so with their own expert testimony – as they have proposed to do." 2018 WL 563144, at *16.

Defendants also argue that Mr. Johnston's opinion is flawed because he opines on the likelihood of succeeding on issues that Forest and Mylan did not intend to raise at trial. Defendants point to a "301-page pretrial order, which includes 187 pages of proposed findings of fact and conclusions of law from both sides" in the '703 patent case that Forest and Mylan were prepared to try. (Defs. Mot. to Exclude at 8.) Defendants complain that many of Mr. Johnston's opinions raise issues and legal arguments that were either undeveloped or completely absent from the parties' pretrial order.

However, Defendants have failed to identify any issue raised by Mr. Johnston that cannot be traced back to documentary evidence related to at least one of the Mylan's defenses identified in its pretrial order. That specific cases or facts were not identified with sufficient granularity in the pretrial order does not justify tying Mr. Johnston's hands. As Defendants do not point to either facts or case law that would justify such a conservative approach, the Court refuses to accept this argument. That said, if Mr. Johnson really did go beyond the issues that were actually in the Mylan-Forest litigation, it should be an interesting cross-examination.

Defendants also protest that Mr. Johnston's opinions constitute impermissible legal opinions and conclusions. However, this is a complex antitrust case involving a secondary body of law – here, patent law – that is not directly at issue. Given the nature of what Mr. Johnston was asked to opine on – the likelihood of success in a patent suit – he necessarily incorporates patent law into his opinion. The Court will not exclude this analysis. As I held with respect to Professor

John Thomas's legal testimony, if Mr. Johnston strays beyond into matters that are irrelevant or otherwise inadmissible, I will be the first to disallow it.

Finally, Defendants complain that Mr. Johnston is not allowed to provide opinions that undermine the statutory presumption of patent validity – a presumption, they argue, that can be overturned only by clear and convincing evidence. After a review of the challenged portions of Mr. Johnston's report, it is clear that his opinions do nothing of the sort. (*See* Johnston Rep. ¶ 76 – 86; 87 – 109; 112 – 20.) Again, Defendants are free to cross-examine Mr. Johnston and to argue that he gave insufficient weight to that hard-to-disprove presumption.

Defendants' motion is DENIED.

II. DEFENDANTS' SUMMARY JUDGMENT MOTION AND PLAINTIFFS' MOTION FOR CLASS CERTIFICATION

Factual Background

This case's factual background and relevant regulatory scheme have been recounted at length in the Honorable Judge Sweet's opinion granting a preliminary injunction to New York, *New York v. Actavis, PLC (Namenda I)*, No. 14 Civ. 7473, 2014 WL 7015198, at *1 (S.D.N.Y. Dec. 11, 2014), the Second Circuit's decision affirming Judge Sweet's opinion, *New York ex rel. Schneiderman v. Actavis PLC (Namenda II)*, 787 F.3d 638 (2d Cir. 2015), *cert. dismissed*, 136 S. Ct. 581, 193 (2015), as well as in two prior decisions of this Court – the first denying Forest's motion to dismiss, *Sergeants Benevolent Association Health & Welfare Fund v. Actavis, PLC (Namenda III)*, Nos. 15 Civ. 6549, 15 Civ. 7488, 2016 WL 4992690, at *1-*8 (S.D.N.Y. Sept. 13, 2016) – and another granting in part and denying in part Plaintiff's motion for collateral

estoppel and partial summary judgment, *In re Namenda Direct Purchaser Antitrust Litigation (Namenda IV)*, No. 15 Civ. 7488 (CM), 2017 WL 4358244, at *1 (S.D.N.Y. May 23, 2017).[3]

In light of these prior rulings, the Court will not recite all of the facts of this case, but instead addresses only the factual and procedural background relevant to the motions addressed herein. The summary of facts in the following pages is drawn from *Namenda I–IV*, as well as from Defendants' Rule 56.1 Corrected Statement of Undisputed Material Facts ("DSoF"), Plaintiffs' Responses and Objections to DSoF ("PRSoF"), Plaintiffs' Affirmative Statement of Material Facts ("PASoF"), and Defendants' Objections and Responses to PASoF ("DRASoF"). Unless otherwise noted, these facts are not in dispute.

Parties

Forest manufactures and sells brand name pharmaceutical products, including the prescription pharmaceutical memantine hydrochloride ("memantine"), which is sold in the United States under the trade names "Namenda" (referred to here as "Namenda IR" to distinguish from Namenda XR) and "Namenda XR. " *Namenda IV*, 2017 WL 4358244, at *2. Memantine is a treatment for moderate-to-severe forms of Alzheimer's disease. Forest developed Namenda IR pursuant to an exclusive license and cooperation agreement with Merz GmbH & Co. KGaA, Merz Pharma GmbH & Co. KGaA, and Merz Pharmaceuticals GmbH (collectively, "Merz Entities"), which owned the relevant patent for a memantine-based drug.[4] *Id.*

[3] Unless otherwise noted, all references to the *Namenda* opinions are to the public, redacted versions where applicable.

[4] The Merz Entities were originally named defendants to some of the counts in the amended complaint. On April 20, 2017, the parties entered a stipulation naming Forest Laboratories, Inc. and Forest Laboratories Holdings Ltd. as defendants to Counts III, IV, and V, and dismissing the Merz Entities as defendants (*See* Dkt. No. 207.)

Named Plaintiff Smith is a South Carolina corporation that purchased Namenda IR directly from Forest. Smith alleges that, during the class period, it paid prices higher than it would have absent Defendants' anticompetitive conduct. *Id.*

Named Plaintiff RDC is a New York corporation that also purchased Namenda IR directly from Forest which it alleges were at supracompetitive prices.[5] *Id.*

Regulatory Background

This case involves the rules set forth in (1) the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, which governs the manufacture, sale, and marketing of pharmaceuticals in the United States; and (2) the Drug Price Competition and Patent Term Restoration Act (the "Hatch-Waxman Act"), Pub. L. No. 98-417, 98 Stat. 1585; *id.* at *2 -*3.

Under the FDCA, a pharmaceutical company must submit a New Drug Application ("NDA") to the FDA before it may bring a new drug to market. *See generally* 21 U.S.C. § 355; *Namenda IV*, 2017 WL 4358244, at *2. Because the NDA must provide the FDA with sufficient scientific data to demonstrate that the new drug is safe and effective, the testing and approval process is generally "long, comprehensive, and costly." *FTC v. Actavis, Inc.*, 570 U.S. 136, 142 (2013); *Namenda IV*, 2017 WL 4358244, at *2. Once approved, though, a patented drug enjoys a period of market exclusivity. *Namenda IV*, 2017 WL 4358244, at *2. That period ends when the drug's patent expires and one or more low-cost generic versions of the drug enter the market and compete with the brand-name drug – what is referred to as going off the "patent cliff." *Namenda II*, 787 F.3d at 643.

[5] On December 28, 2015, RDC filed an identical complaint against Forest and Merz. All parties stipulated to consolidation of the two duplicative actions, with the Smith Complaint serving as the operative complaint in the consolidated action (*see* Dkt. No. 12, Case No. 15 Civ. 10083), and an amended caption to reflect consolidation: *In Re Namenda Direct Purchaser Antirust Litigation*. (*See* Dkt. No. 22, Case No. 15 Civ. 10083.)

The Hatch-Waxman Act makes it easier for manufacturers of generic drugs to compete with brand-name drug producers. *Namenda IV*, 2017 WL 4358244, at *3. As relevant here, the Hatch-Waxman Act provides two methods by which a brand-name drug manufacturer can extend its period of market exclusivity. *Id.*

First, a manufacturer can seek an extension of its patent from the USPTO to account for the time the manufacturer spent obtaining approval from the FDA for its brand-name drug. 35 U.S.C. § 156. That extension can last no more than five years. *Id.* at § 156(g)(6); *Namenda IV*, 2017 WL 4358244, at *3.

Second, a brand-name drug manufacturer can obtain a six-month period of "pediatric exclusivity" if it conducts certain pediatric studies and the FDA determines that use of the drug in children may produce health benefits. 21 U.S.C. § 355a. A grant of pediatric exclusivity does not extend the length of the underlying patent, but can operate to exclude generic competition by delaying the date by which the FDA may approve generics for sale. *Namenda IV*, 2017 WL 4358244, at *3.

Under the Hatch-Waxman Act, the manufacturer of a generic version of an FDA-approved drug may file an Abbreviated New Drug Application ("ANDA"), which allows the generic manufacturer to rely upon the studies submitted by the brand-name drug manufacturer in connection with the original NDA to prove that the generic version of the drug is safe and effective. *Id.* The ANDA filer must certify that its generic drug, among other things, has the same active ingredient as, and is "bioequivalent" to, the previously-approved drug. 21 U.S.C. § 355(j)(2)(A)(ii), (iv); *Namenda II*, 787 F.3d at 644. A generic drug is bioequivalent to the brand-name drug if it has the same "rate and extent of absorption" of the active ingredient as that of the brand-name drug. 21 U.S.C. § 355(j)(8)(B)(i); *Namenda IV*, 2017 WL 4358244, at *3. "In other

words, two drugs are bio equivalent if they deliver the same amount of the same active ingredient content into a patient's blood stream over the same amount of time." *Namenda II*, 787 F.3d at 644.

Facts of the Case

A. Settlement Agreements

Forest launched Namenda IR in the United States in January 2004, under the '703 Patent, which granted Forest the exclusive right to market a memantine-based drug in the United States. *Namenda IV*, 2017 WL 4358244, at *5. Forest then applied for and received a five-year extension to the '703 Patent, which was set to expire in April 2010 (an extension permitted under 35 U.S.C. § 156 for the time Forest spent obtaining FDA approval). *Id.* Namenda IR was also approved for six months of pediatric exclusivity in June 2004. *Id.* at *6.

At least 17 generic drug manufacturers filed ANDAs seeking to market generic versions of Namenda IR. *Id.* Defendants timely brought suits for patent infringement, but ultimately reached a number of settlement agreements. *Id.* Each agreement contained a virtually identical provision that Plaintiffs assert was anticompetitive, which granted the competitors a license to begin selling a generic version of Namenda IR beginning three months prior to the later of: (1) the expiration of the '703 Patent or (2) the end of any pediatric exclusivity period attached to the '703 Patent. *Id.* With the six-month exclusivity period in place, this meant that the generic competitors could not begin selling generic versions of Namenda IR until July 11, 2015. *Id.*

B. The "Hard Switch"

Forest obtained FDA approval for Namenda XR in June 2010 and began marketing Namenda XR in July 2013. *Id.* at *7. Namenda IR and Namenda XR contain the same active ingredient and have the same therapeutic effect, but Namenda IR is a tablet taken twice a day that releases directly into the bloodstream while Namenda XR is a capsule that is taken once a

day and releases gradually. *Id.* They are not, therefore, "bioequivalents" under the FDA's definition of that term, and so cannot be substituted for one another under any drug substitution law that requires substitutes to be certified by the FDA as bioequivalents. Similarly, generic drugs that are bioequivalents of Namenda IR cannot be substituted for Namenda XR under the same standards.

The key non-pharmacological difference between Namenda IR and Namenda XR relates to their patent protection. Namenda XR's period of patent exclusivity does not expire until 2029, while Namenda IR's expired in 2015. *Namenda II*, 787 F.3d at 647.

When Forest brought Namenda XR to market in 2013, it engaged in a variety of "soft-switch" tactics to encourage patients and physicians to convert from Namenda IR to Namenda XR before Namenda IR lost its patent protection in 2015. *See id.* at 647 – 48. For example, it priced Namenda XR below Namenda IR; it stopped actively marketing Namenda IR; and it heavily promoted the benefits of Namenda XR, including its lower price and once-daily dosage. *Namenda IV*, 2017 WL 4358244, at *7.

Judge Sweet concluded in *Namenda I* that Forest executives were concerned about the company's ability to convince a sufficient number of patients to convert to Namenda XR prior to generic entry, making a "hard switch" necessary. *Namenda I*, 2014 WL 7015198, at *18. It is undisputed that, on February 14, 2014, Forest announced by press release, notice to the FDA, and letters to physicians and patients, that it was taking Namenda IR off the market on August 15, 2014. *Id.* Four months later, however, Forest announced that it would continue selling Namenda IR through the fall of 2014 due to manufacturing issues with Namenda XR. *Id.* at 22.

C. The Mylan Reverse Payment Agreement

By 2002, Forest had a license to market a drug named Lexapro. (DSoF ¶ 180.) On October 3, 2005, Forest and Alphapharm (later acquired by Mylan), entered into a distribution and supply agreement for authorized generic Lexapro ("the Original Lexapro Agreement.") (*Id.* at ¶ 182.) By the terms of the Original Lexapro Agreement, Forest would supply Alphapharm's requirements of generic Lexapro for sale and distribution, and Alphapharm would market, but not manufacture, an authorized generic version of Lexapro. (*Id.* at ¶ 184 – 87.)

Alphapharm agreed to pay Forest a 40% share of its "product profit," which the agreement defined as Alphapharm's net sales less Forest's manufacturing costs. (*Id.* at ¶ 189 – 90.)

The '712 Patent was set to expire on March 12, 2012, at which point Teva, the sole first-filing ANDA applicant, was permitted to launch its version of generic Lexapro on March 12, 2012 and was entitled to 180 days of exclusivity under the Hatch-Waxman Act, in that the FDA would not finally approve another ADNA during that time. (DSoF ¶ 194; PRSoF ¶ 194.) Under the Agreement, Alphapharm was allowed to launch its authorized generic two weeks before Teva's date of entry on February 27, 2012. (*Id.* at ¶¶ 188, 193; PRSoF ¶ 193.) The Original Lexapro Agreement had a five year term (starting with Lexapro patent expiry), with a one-year minimum. (PRSoF ¶ 218(e).) Mylan acquired Alphapharm in 2007. (DSoF ¶ 218.)

The Medicaid Drug Rebate Program ("MDRP"), which was established by Congress in 1990, required brand manufacturers to pay a rebate to the government on prescription drugs reimbursed by Medicaid. (DSoF ¶ 197.) The MDRP requires participating drug manufacturers to pay a rebate on those drugs for which a state's Medicaid agency has paid pharmacies to dispense the drug to Medicaid beneficiaries. (*Id.* at ¶ 198.) To determine the rebate amount owed by a

manufacturer, the Centers for Medicare & Medicaid Services ("CMS") calculates a per-unit rebate amount ("URA") based on a statutory formula. (*Id.* at ¶ 199.)

The URA for a drug is tied to a product's "Best Price" or, "the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States…" (*Id.* at ¶ 200.) The URA is calculated, in part, using a brand manufacturer's commercial sales and discount data. (*Id.* at ¶ 201.)

The Deficit Reduction Act of 2005 ("DRA"), in large part, became effective on January 1, 2007. (*Id.* at ¶ 202.) The Final Rule implementing the DRA (the "DRA Final Rule") became effective October 1, 2007. (*Id.* at ¶ 203.) The DRA amended the definition of Best Price to include, for the first time, the lowest price of an authorized generic drug. (*Id.* at ¶ 206.) On January 23, 2008, the CMS clarified that the DRA Final Rule "provides that the primary manufacturer include the best price of an authorized generic drug in its calculation of best price when the drug being sold by the primary manufacturer to the secondary manufacturer. In accordance with this provision, we expect that the primary manufacturer report a BP [best price] which incorporates the transfer price at the time of sale to the secondary manufacturer for the quarter in which the sale occurs, regardless of when the product is launched." (*Id.* at ¶ 207.) The transfer price is generally reflective of the cost to manufacture a drug. (*Id.* at ¶ 209.)

Under the Original Lexapro Agreement, Forest was a primary manufacturer, and Alphapharm was a secondary manufacturer. (*Id.* at ¶ 208.) Generally, the lower a manufacturer's best price is, the higher its Medicaid Rebate liability will be. (*Id.* at ¶ 212.)

It is undisputed that the DRA exposed Forest to more Medicaid liability than it was exposed to when it entered the agreement in 2005, since under the new rule Forest would now

have to include the best price of generic Lexapro in its calculation of best price. (*Id.* at ¶ 208 – 14; PRSoF ¶ 214.) It is also undisputed that the parties negotiated and amended its Lexapro Agreement ("the Lexapro Amendment"), which was executed on July 21, 2010. (DSoF ¶ 255.)

The parties dispute, however, the content and validity of Forest's cost-benefit analysis while it was negotiating the Lexapro Amendment.

According to Defendants, Forest performed three analyses to assess the potential benefits of amending the Original Lexapro Agreement: (1) a comparison of Forest's post-DRA Medicaid Liability under the Original Lexapro Agreement and Forest's liability pursuant to a potential amendment requiring Mylan to manufacture generic Lexapro ("Medicaid Liability Analysis"), (2) a forecast projecting Forest's profit share revenue under the Original Lexapro Agreement and a potential amendment to that agreement ("The Lexapro Sales Forecasts"), and (3) a projection of the potential costs of goods sold savings Mylan could achieve if it manufactured generic Lexapro ("COGS Summary"). (DSoF ¶ 215.)

According to Plaintiffs, the documents underlying Forest's analysis are unreliable. Plaintiffs point out that the final analyses were not created until after Forest and Mylan told the Namenda IR patent court that it had reached a settlement in principle; thus, they could not have been performed to assess the "potential benefits" of the transaction, which had already been agreed to. (PRSoF ¶ 214.)

D. The Other Reverse Payments

The parties do not provide the Court with the same level of detail about the other reverse payment agreements. Here is what we know: Forest settled with approximately eleven generic companies, with each settlement providing for up to a $2 million cash payment, and generic launch dates three months prior to Forest's statutory exclusivity, absent any extension for

pediatric exclusivity or the triggering of the accelerated launch provisions if other generics came in early.

Procedural History

There have been two dispositive motions in this case.

On September 13, 2016, this Court denied Defendants' motion to dismiss – finding, in brief, that Plaintiffs stated a claim for product hopping (based on the planned "hard switch"), stated a claim based on the settlement agreements with generic manufacturers, and Plaintiff claims were not time-barred. (Dkt. No. 106.) This Court dismissed Plaintiffs' overarching scheme claim (Count II) as duplicative. (*See id.*)

A few months later, Plaintiffs moved for collateral estoppel and partial summary judgment on Count One (Dkt. No. 134) and for partial summary judgment on Count Five (Dkt. No. 138). Defendants cross-moved for partial summary judgment on Count Five (Dkt. No. 161). On May 23, 2017, this Court denied both motions for partial summary judgment on Count IV. This Court also granted Plaintiffs' motion for collateral estoppel, finding:

> Because all of the elements of collateral estoppel are met, Forest is precluded from relitigating the questions of (1) whether it possessed monopoly power over the U.S. memantine market up until the entry of generic competition; (2) whether its February 2014 announcement of the upcoming discontinuation of Namenda IR was coercive and anticompetitive; and (3) whether Forest had any non-pretextual procompetitive justification for its illegal conduct. Plaintiffs' motion for collateral estoppel on these issues of fact is GRANTED. They will be presented to the jury as already decided.

Namenda IV, 2017 WL 4358244, at *16.

This Court, however, denied Plaintiffs' motion for partial summary judgment on Count One since outstanding questions of material fact remained regarding antitrust injury, which is a necessary element of Plaintiffs' Section 2 claim.

Defendants now move for summary judgment dismissing all claims in Plaintiffs' First Amended Complaint. (Dkt. No. 434.)

Plaintiffs move to certify a class comprised of 62 direct purchasers of Namenda. (Dkt. No. 400.)

Discussion

Summary Judgment Standard

A party is entitled to summary judgment when there is no "genuine issue of material fact" and the undisputed facts warrant judgment for the moving party as a matter of law. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242 (1986); *see also* Fed. R. Civ. P. 56. In addressing a motion for summary judgment, "[t]he court must view the evidence in the light most favorable to the party against whom summary judgment is sought and must draw all reasonable inferences in [its] favor." *L.B. Foster Co. v. Am. Piles, Inc.*, 138 F.3d 81, 87 (2d Cir. 1998). Whether any disputed issue of fact exists is for the Court to determine. *See Balderman v. United States Veterans Admin.*, 870 F.2d 57, 60 (2d Cir. 1989). The moving party has the initial burden of demonstrating the absence of a disputed issue of material fact. *See Celotex v. Catrett*, 477 U.S. 317, 323 (1986). Once such a showing has been made, the nonmoving party must present "specific facts showing that there is a genuine issue for trial." *El-Nahal v. Yassky*, 835 F.3d 248, 256 (2d Cir. 2016), *cert. denied*, 137 S. Ct. 2187 (2017) (internal quotation marks and citations omitted). The party opposing summary judgment "may not rely on conclusory allegations or unsubstantiated speculation." *Scotto v. Almenas*, 143 F.3d 105, 114 (2d Cir. 1998).

Moreover, not every disputed factual issue is material in light of the substantive law that governs the case. "Only disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment." *Anderson*, 477 U.S. at 248. Finally, the nonmoving party "must do more than simply show that there is some metaphysical

doubt as to the material facts." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). To withstand a summary judgment motion, sufficient evidence must exist upon which a reasonable jury could return a verdict for the nonmovant. With these principles in mind, I turn to the claims presented.

Analysis

Defendants move for summary judgment dismissing all claims.

All remaining claims assert that Defendants violated the Sherman Antitrust Act. Count I alleges unlawful maintenance of monopoly power under Section 2 of the Sherman Act for forcing Namenda IR consumers to switch to Namenda XR. Count III alleges unlawful maintenance of monopoly power under Section 2 of the Sherman Act for entering into agreements with generic manufacturers to delay generic entry for three months past the expiration of the '703 patent. And Counts IV and V allege restraint of trade under Section 1 of the Sherman Act for entering into agreements with potential generic manufacturers to delay their entry into the market for three months beyond the expiration of the '703 patent term.

Defendants have moved for summary judgment on the following grounds: (1) there is no evidence in the summary judgment record that Forest's settlements with the generic manufacturers contained an unlawful reverse payment; (2) there is no triable issue of fact related to Plaintiffs' overarching conspiracy claim; (3) Plaintiffs have failed to make the requisite showings of causation; and (4) Plaintiffs have failed to establish that they have suffered antitrust injury as a result of Forest's February 2014 announcement.

A. Plaintiffs' Overarching Conspiracy Claim Was Dismissed

As an initial matter, Forest's motion for summary judgment on Plaintiffs' "overarching conspiracy claim," which was Count II of their complaint is moot. (*See* Am. Compl., Dkt. No. 26

at ¶¶ 244 – 50.) As mentioned above, this Court dismissed this count in its September 13, 2016 decision on Defendants' motions to dismiss. (*See* Dkt. No. 106 at 33.)

Moreover, Plaintiffs have abandoned their inter-generic conspiracy claim (Count IV). (*See* Pls.' Mem. of Law in Opp'n to Defs. Mot. for Summary Judgment at 1.)

There are genuine issues of material fact precluding summary judgment with respect to Forest's two other grounds for summary judgment, which I address in turn below.

B. Defendants' Motion for Summary Judgment on all Claims Arising from Forest's Alleged Reverse Payments to Generic Manufacturers is DENIED

Defendants move for summary judgment on all claims arising from Forest's patent settlement agreements with generics, arguing that Forest made no illegal reverse payments as part of their settling of the various Namenda patent challenges.

The Court concludes that Plaintiffs have offered sufficient evidence such that a reasonable juror could find that Forest's payments to generics did not merely compensate them for avoided litigation costs or fair value for services – and thus were large and unjustified reverse payment in violation of the antitrust laws.

1. Which Settlement Agreements Are at Issue

As an initial matter, Forest argues that discovery eliminated the vast majority of Plaintiffs' reverse payment claims. In their First Amended Class Action Complaint (Dkt. No. 29), Plaintiffs asserted that Forest entered into anticompetitive reverse payment settlement agreements with approximately eleven first filer generic manufacturers. (Am. Compl. at ¶ 113.) Forest contends that, after discovery failed to support their wide-ranging allegations, Plaintiffs functionally abandoned their challenges to all but one of these agreements – the Forest-Mylan Agreement.

The following discussion analyzes the Forest-Mylan Agreement only. The fact remains, however, that the anticompetitive conduct at issue in this case is premised on the alleged barriers to entry put in place by Forest to prevent *all* generic competition, not just Mylan's. Given that the Forest-Mylan settlement was the very last patent settlement agreement Forest entered into, all of the other settlements to keep generic companies from competing that were signed before the Forest-Mylan settlement undergird and compound the anticompetitive effect of the Forest-Mylan deal. This fact is well-illustrated by a February 11, 2010 Forest-Mylan settlement presentation, in which Forest explained that if Mylan would have won the Namenda patent litigation, there would have been "No Financial Upside" because Mylan's profits would have been "miniscule" due to the . . . prior settling Namenda generics having provisions in their agreements that provided for immediate and simultaneous market entry if Mylan won the patent dispute, [thereby] lowering Mylan's potential generic Namenda profits." PASoF ¶ 236 – 37.

Nonetheless, Forest argues that Plaintiffs have abandoned their claims relating to all but Mylan. As a result, in the papers supporting its motion, Forest does not make a particularized showing about why summary judgment should be granted with regard to any of the other agreements that were identified in the complaint as anticompetitive. It simply asserts that Plaintiffs have abandoned those claims, and offers evidence and argument about why the Forest-Mylan settlement does not violate the antitrust laws.

Plaintiffs have taken no affirmative steps to indicate that it has abandoned all claims related to its other eleven or so alleged reverse payments – that is simply an assertion by Forest. In its responsive papers, it neither agrees with Forest that those claims have been abandoned nor offers any evidence that would tend to show that the agreements were in fact anti-competitive. Of course, as the party opposing the motion for summary judgment, Plaintiffs had no obligation

to discuss agreements that were not addressed on the merits by Forest. But they should have addressed Forest's contention that they were abandoning those claims.

I am going to address the Forest-Mylan agreement, as to which there are myriad genuine issues of material fact that preclude summary judgment. Plaintiffs have ten days from the date of this decision to advise the Court whether they are pursuing claims related to the other reverse payment agreements. If they are, we will simply take those claims to trial.

2. Legal Standards

In *F.T.C. v. Actavis, Inc.*, 570 U.S. 136 (2013), the Supreme Court held that a reverse payment settlement – that is, a payment by a patentee to a claimed infringer – is not presumptively either lawful or unlawful, but will be subject to antitrust scrutiny in certain circumstances. Reverse payments are of particular concern when they demonstrate "that the patentee [sought] to induce the . . . [infringer] to abandon its claim with a share of its monopoly profits that would otherwise be lost in the competitive market." *Id.* at 154. To violate antitrust law, a reverse payment must be both "large and unjustified." *Id.* at 158.

A payment's size may indicate that "the patentee likely possesses the power to bring [an unjustified anticompetitive] harm about in practice." *Id.* at 157. In other words, a large reverse payment may signal that the patentee possessed "the power to charge prices higher than the competitive level" and may be using that power to keep others from entering its market. *Id.* Such a payment may also indicate a patent holder's concern about the validity of its patent, such that "the size of the payment may very well correspond with the magnitude of that concern." *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 251 (3d Cir. 2017), *cert. denied sub nom. Pfizer Inc. v. Rite Aid Corp.*, 138 S. Ct. 983 (2018), and *cert. denied sub nom. Wyeth LLC v. Rite Aid Corp.*, 138 S. Ct. 984 (2018).

The Supreme Court in *Actavis*, however, acknowledged that there also might be "legitimate justification[s]" for a reverse payment settlement, including, but not limited to, "avoided litigation costs or fair value for services." *Actavis*, 570 U.S. at 156. The Court directed district courts to apply the traditional rule of reason analysis when evaluating reverse payment settlements. *See id.*

> Rule of reason analysis proceeds in three steps. First, the plaintiff bears the initial burden of showing that the defendant's conduct "had an actual adverse effect on competition as a whole in the relevant market." *Capital Imaging Assocs., P.C. v. Mohawk Valley Med. Assocs., Inc.*, 996 F.2d 537, 543 (2d Cir. 1993) (emphasis in original). If plaintiff satisfies this burden, the burden then shifts to defendant to offer evidence that its conduct had pro-competitive effects. *Id.* If defendant is able to offer such proof, the burden shifts back to plaintiff, who must prove that any legitimate competitive effects could have been achieved through less restrictive alternatives. *Id.*

Arkansas Carpenters Health & Welfare Fund v. Bayer AG, 604 F.3d 98, 104 (2d Cir. 2010), as corrected (June 17, 2010).

"To survive summary judgment, the plaintiffs must present a 'genuinely disputed issue of material fact' as to the elements of the rule of reason analysis; only then will the case go to a jury." *In re Wellbutrin XL Antitrust Litig.*, 133 F. Supp. 3d 734, 754 (E.D. Pa. 2015), *aff'd sub nom. In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132 (3d Cir. 2017), *judgment entered sub nom. In re Wellbutrin XL Antitrust Litig.*, No. 15 Civ. 2875, 2017 WL 3529114 (3d Cir. Aug. 9, 2017).

3. Reverse Payment Analysis

This Court predicted in *Namenda IV* that, "Whether the settlement agreements were anticompetitive or procompetitive will depend on several complex factual questions that cannot be decided on summary judgment." 2017 WL 4358244, at *19. As demonstrated by the host of

genuine issues of material fact emanating from the papers filed in connection with this motion, I was correct.

In their briefing on the alleged unlawful reverse payment, the parties analyze several components of the Forest-Mylan agreement, including a cash payment from Forest to Mylan, an agreed early entry date with the possibility of acceleration, and the Lexapro Amendment. Since I am denying the motion, I will use the Lexapro Amendment to illustrate why.[6]

The Court finds that Plaintiffs have offered enough evidence to allow a reasonable finder of fact to conclude that Plaintiffs have established a *prima facie* case for imposing antitrust liability. Although Defendants have offered procompetitive justifications for the Lexapro Amendment –particularly evidence that may indicate that the Lexapro Amendment was a fair market value deal – Plaintiffs have offered some evidence that the Amendment was not fair, but instead, constituted overcompensation for agreeing not to compete.

a. Lexapro Amendment

The initial burden of proof lies with Plaintiffs, who must show that Defendants' conduct had an actual adverse effect on competition.

As a threshold issue, the parties disagree about whether the Lexapro Amendment was even a part of the Forest-Mylan patent settlement.

Forest claims that its in-house counsel negotiated the Namenda patent settlement with Mylan and that a "largely separate team" of Forest business people negotiated the Lexapro Amendment with Mylan. Nonetheless, it is undisputed that both the settlement agreement and

[6] Because Plaintiffs have raised genuine issues of material fact regarding whether the Lexapro Amendment constituted an unlawful reverse payment, they have likewise raised genuine issues of material fact as to whether the deal, taken as a whole, constituted an unlawful reverse payment. The Court need not discuss each component. All claims related to Forest's settlement agreements with Mylan will go to trial.

Lexapro Amendment were executed on the same day, July 21, 2010, and that there were certain personnel of whom were aware of both agreements. (PASoF ¶ 239.)

Plaintiffs, on the other hand, contend that the Lexapro Amendment was linked to the Namenda patent settlement. As evidence, they point to Mylan Deal Concept documents reflecting the "proposed structure" of the Namenda patent settlement, which featured the amendment to the Original Lexapro Agreement. (PASoF ¶ 229.) The January 20 document listed, as "Potential Transaction Benefits to Mylan," "at least $1.5MM in manufacturing cost savings gained through Mylan's control of drug product manufacturing and packaging[.]" (PASoF ¶ 232.) Plaintiffs also point to Forest's in-house and outside counsel repeatedly referring to the Lexapro Amendment as a "side-deal" to the Namenda patent dispute (PASoF ¶ 243), along with a February 11, 2010 Forest-Mylan meeting presentation that explicitly presents the Lexapro Amendment and Namenda patent settlement as a package. (PASoF ¶ 240.)

On this point, Plaintiffs have presented enough evidence to allow a rational juror to conclude that the Lexapro Agreement was a part of the Forest-Mylan patent settlement.

Plaintiffs have also presented sufficient evidence to allow a rational juror to conclude that the Lexapro Amendment had an anticompetitive effect that outweighed its procompetitive effects.

Forest contends that the Lexapro Amendment did not disguise a payment for delayed generic entry, but was instead a fair value business deal between Forest and Mylan, based on arm's length negotiations and reasonable business expectations at the time of the agreement. Plaintiffs counter that the Lexapro Amendment was both large and unjustified. They claim that the Lexapro Amendment conferred $32.5 million to Mylan – ten times Forest's saved litigation costs of $3.5 million. (PRSoF ¶ 280.) Plaintiffs point again to Forest's 2011 settlement

presentation, in which Forest points out that "the money it was proposing to pay to Mylan – including 'millions of dollars' from modifying the 'LEXAPRO authorized generic deal' – 'provides *more* value than Mylan's forecasted profits for generic memantine[.]" (PASoF ¶ 235-38 (emphasis added).)

This admission is enough to create a genuine issue of material fact. "A reasonable jury could find that a reverse payment to a generic manufacturer that comes close to or exceeds the expected profits to be earned by prevailing in the patent litigation could induce a generic manufacturer to forfeit its claim." *King Drug Co. of Florence v. Cephalon, Inc.*, 88 F. Supp. 3d 402, 417 (E.D. Pa. 2015).

Part of Forest's explanation for the $32.5 million reverse payment is that it compensated Mylan for accepting manufacturing responsibility for authorized generic Lexapro, thereby allowing Forest to avoid $26.5 million in Medicaid rebate liability.

Plaintiffs argue that this claimed reduction was both inflated and pretextual. Plaintiffs point out that the final analyses were not created until after Forest and Mylan told the Namenda IR patent court that it had reached a settlement in principle. (PRSoF ¶ 214.) Plaintiffs claim that Forest employees manipulated the rebate liability analyses to inflate the forecasted rebate savings to just about equal the reverse payment to Mylan. They point to convenientlt-timed changes to the royalty rate rates made in March 2010, which inflated the purported rebate savings. (PASoF at ¶¶ 265 – 67.)

Plaintiffs have presented enough evidence that rebuts Defendants' procompetitive justifications to get to trial.

Defendants' motion for summary judgment dismissing Plaintiffs' claims related to Forest's settlement agreements with generics is DENIED.

C. Defendants Are Not Entitled to Summary Judgment Because Plaintiffs Carry Their Burden on Causation

Defendants argue that they are entitled to summary judgment because Plaintiffs have not raised a genuine issue of material fact on the issue of causation.

"Causation in fact is, of course, a necessary element of any claim for relief." *In re Actos End-Payor Antitrust Litig.*, 848 F.3d 89, 97 (2d Cir. 2017) (quoting *Argus Inc. v. Eastman Kodak Co.*, 801 F.2d 38, 41 (2d Cir. 1986). "An antitrust plaintiff must show that a defendant's anticompetitive act was a "material" and "but-for" cause of plaintiff's injury, although not necessarily the sole cause." *In re Actos*, 801 F.2d at 38 (quoting *In re Publ'n Paper Antitrust Litig.*, 690 F.3d 51, 65 – 66 (2d Cir. 2012)). A plaintiff "need not exhaust all possible alternative sources of injury in fulfilling his burden of proving compensable injury." *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 114 n.9 (1969); *see also In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677, 695 (2d Cir. 2009).

Here, Plaintiffs offer two alternative causation theories: (1) but for Forest's reverse payment, Forest and Mylan would have entered a no-payment settlement with an earlier entry date based on the bargaining strength of the parties; and (2) absent a settlement Mylan would have prevailed in the patent litigation and entered earlier than the agreed-to entry date.

Defendants argue that both theories are based on insufficient evidence and are speculative. Against, the Court disagrees.

1. Early Entry Date But for Reverse Payment

Plaintiffs' first causation theory is that the parties would have agreed to an earlier generic entry date but for the alleged reverse payment. Plaintiffs rely primarily on expert opinions to support this causation theory.

As discussed in section I.2, *supra*, Plaintiffs rely on a report from Professor Einer Elhauge addressing what economic analysis reveals about Forest and Mylan's settlement of the Namenda IR patent litigation, including whether an alleged reverse payment from Forest to Mylan delayed generic entry into the market and what the settlement entry date would have been in a no-payment settlement. (*See* Elhauge Rep. ¶ 1.) Professor Elhauge's report was admitted with the caveat that he cannot offer an opinion about when entry "would have" occurred, so as not to usurp the role of the factfinder. Professor Elhauge is, however, allowed to testify that by specific dates "it would have been economically rational for both parties" to enter into a no-payment settlement in a "but for" world (*e.g.*, November 2012). (Elhauge Dep. Tr. at 225:18 – 227:18.)

Forest attacks Professor Elhauge's assertions as speculative and largely repeats the arguments made in its motion to exclude. This Court has already held that it will not prevent Professor Elhauge from offering his opinion on this but-for scenario as a general matter. (*See* section I.2., *supra*.)

Forest argues that the evidence suggests that it would not have agreed to a settlement allowing generic Namenda entry in November 2012. In support of this argument, Forest cites to *post hoc* testimony of its own employees. For example, Forest points to testimony from its Chief Intellectual Property Counsel, who was responsible for overseeing the Namenda patent litigation at the time of the settlement. He testified that a settlement agreement with Mylan allowing generic entry in 2012 would have been neither feasible nor acceptable to Forest. (*See* Hamburger Decl. Ex. 18, Dkt. No. 438 ("Ryan Dep. Tr.") at 394:21 – 395:4.) "At most defendants criticize plaintiffs' experts for failing to consider or adequately consider certain points they believe are

significant . . . disagreements [of which] are the subject for cross-examination." *Lidoderm*, 296 F. Supp. 3d at 1164. It is up to the jury to weigh the evidence.

The evidence raises a "genuine dispute of material fact on this causation theory." *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, No. CV 14-MD-02503, 2018 WL 563144, at *16 (D. Mass. Jan. 25, 2018).

2. Early Entry Date After Mylan Won '703 Patent Litigation

Plaintiffs' second causation theory is that if Forest and Mylan had not settled, Mylan would have likely prevailed in the patent litigation through trial and appeal and entered the market earlier than it did.

While Defendants argue that Plaintiffs may not establish causation and antitrust injury by reference to a hypothetical patent trial between Forest and Mylan, this Court has already held that it could. *See Namenda* III, 2017 WL 4358244, at *19 (The viability of Plaintiffs' Section 1 claim "will depend on the presence of 'evidence suggesting that the settlement agreements did, in fact, delay generic entry,' which will presumably require proof that the '703 Patent would likely have been found invalid or not infringed by the Generic Competitors.")

Defendants point to the patent court's favorable *Markman* ruling and the subsequent settlements by Forest and the generics of the patent challenges as evidence that Forest's patent was unlikely to fail. Plaintiffs counter that the subsequent settlements had nothing to do with the patent merits, but are instead evidence – as Forest explained to Mylan during settlement discussions – that the generics recognized that there was "no financial upside to litigating." (PASoF ¶¶ 56 – 57.) In other words, they argue that the settlements were recognition that there were fourteen first filers who would share the 180-day exclusivity window and that sales and

profits for generic memantine would be miniscule as a result. However, the Court need not resolve this issue for purposes of summary judgment.

As discussed in section I.6.C., *supra*, the court admits the opinions of Plaintiffs' expert George W. Johnson, Esq. Given this testimony, Plaintiffs have proffered evidence sufficient to raise a genuine dispute of material fact on this causation theory.

Defendants' summary judgment motion is DENIED.

D. Defendants are Not Entitled to Summary Judgment on Plaintiffs' Hard Switch Claims

Defendants move for summary judgment on Forest's hard switch claims arguing that Defendants cannot establish that the proposed class members suffered antitrust injury as a result of Forest's February 2014 announcement. In support of this motion, Defendants rely on the same arguments made in their motion to exclude the testimony of Plaintiffs' expert, Dr. Lamb, addressed in section I.3., *supra*. (*See* Dkt. No. 445.)

For the reasons discussed therein, Defendants' motion is DENIED.

Plaintiffs' Motion for Class Certification is GRANTED

Class Certification Standard

Rule 23 of the Federal Rules of Civil Procedure governs class certification. "The Second Circuit has emphasized that Rule 23 should be given liberal rather than restrictive construction, and it seems beyond peradventure that the Second Circuit's general preference is for granting rather than denying class certification." *Espinoza v. 953 Assocs. LLC*, No. 10 Civ. 5517 (SAS), 2011 WL 5574895, at *6 (S.D.N.Y. Nov. 16, 2011) (quoting *Gortat v. Capala Bros., Inc.*, 257 F.R.D. 353, 361 (E.D.N.Y. 2009), *aff'd*, 568 F. App'x 78 (2d Cir. 2014)).

A. Rule 23(a)

A putative class must meet the four prerequisites set forth in Rule 23(a) to be certified: numerosity, commonality, typicality, and adequacy of representation. *Brown v. Kelly*, 609 F.3d 467, 475 (2d Cir. 2010).

If even one of the Rule 23(a) requirements is not met, certification must be denied. *Gomez v. Lace Entm't, Inc.*, No. 15 Civ. 3326 (CM), 2017 WL 129130, at *4 (S.D.N.Y. Jan. 6, 2017). As the Supreme Court observed in *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 349 (2011), the requirements of Rule 23, by effectively confining the class claims to those "fairly encompassed" by the claims of the named plaintiffs, ensure that those plaintiffs are "appropriate representatives of the class whose claims they wish to litigate."

1. Numerosity – Rule 23(a)(1)

Numerosity requires that the class must be "so numerous that joinder of all members is impracticable." Fed. R. Civ. P. 23(a)(1). As certain presumptions attach depending on the sheer size of the class, the number of members in a putative class is the starting point of the Rule 23(a)(1) analysis. Classes with forty or more putative members raise a rebuttable presumption that joinder is impracticable. *See Sanchez v. New York Kimchi Catering, Corp.*, 320 F.R.D. 366, 375 (S.D.N.Y. 2017); *Shayler v. Midtown Investigations, Ltd.*, No. 12 Civ. 4685 (KBF), 2013 WL 772818, at *4 (S.D.N.Y. Feb. 27, 2013). For classes with fewer than twenty members, however, joinder is generally deemed practical. *See, e.g.*, *Ansari v. New York Univ.*, 179 F.R.D. 112, 114 (S.D.N.Y. 1998) (twenty-one or fewer members suggests no class); *CL–Alexanders Laing & Cruickshank v. Goldfeld*, 127 F.R.D. 454, 455 (S.D.N.Y. 1985) (twenty-one members insufficient to certify class); *see also Wilson v. Corelogic SafeRent, LLC*, No. 14 Civ. 2477

(JPO), 2017 WL 4357568, at *6 (S.D.N.Y. Sept. 29, 2017) (quoting William B. Rubenstein, *Newberg on Class Actions* § 3:11 (5th ed. 2017)).

Keeping in mind that the inquiry is not strictly mathematical, *Pa. Pub. Sch. Empls. Ret. Sys. v. Morgan Stanley & Co., Inc.*, 772 F.3d 111, 120 (2d Cir. 2014), the district court must analyze each case separately to determine whether the numerosity requirement has been satisfied, considering the following factors:

1. judicial economy;
2. geographic dispersion of the proposed class members;
3. financial resources of the proposed class members;
4. the ability of proposed class members to file individual suits;
5. requests for relief that could affect future class members;
6. knowledge of the names and existence of potential class members; and
7. whether potential class members have already joined in other actions.

See Robidoux, 987 F.2d at 935.

2. Commonality – Rule 23(a)(2)

Commonality requires that there exist questions of law or fact that are both common to the class and answerable through a class-wide proceeding. Fed. R. Civ. P. 23(a)(2); *Dial Corp. v. News Corp.*, 314 F.R.D. 108, 113 (S.D.N.Y. 2015). The Supreme Court has clarified that this prong also requires the plaintiff to "demonstrate that the class members 'have suffered the same injury.'" *Wal–Mart*, 564 U.S. at 350 (quoting *Gen. Tel. Co. of Southwest* v. *Falcon*, 457 U.S. 147, 157 (2011)). Where, as here, plaintiffs move to certify a class under Rule 23(b)(3), the commonality requirement is subsumed under, or superseded by, the more demanding predominance requirement of Rule 23(b)(3), discussed *infra*. *See Dial*, 314 F.R.D. at 113.

3. Typicality – Rule 23(a)(3)

Typicality "is satisfied when each class member's claim arises from the same course of events, and each class member makes similar legal arguments to prove the defendant's liability." *Marisol A. v. Giuliani*, 126 F.3d 372, 376 (2d Cir. 1997) (internal quotation marks omitted) (quoting *In re Drexel Burnham Lambert*, 960 F.2d 285, 291 (2d Cir. 1992)). Similar considerations animate commonality and typicality such that the analyses under Rules 23(a)(2) and (3) tend to merge. *See Marisol A.*, 126 F.3d at 376.

4. Adequacy – Rule 23(a)(4)

Adequacy requires that "the representative parties fairly and adequately protect the interests of the class." Fed. R. Civ. P. 23(a)(4); *see also Brown*, 609 F.3d at 475. Class counsel must be "qualified, experienced, and generally able to conduct the litigation." *Marisol A*, 126 F.3d at 378 (internal quotation marks omitted) (quoting *In re Drexel Burnham Lambert Grp, Inc.*, 960 F.2d at 291).

Rule 23(a)(4) also requires that the class representative "be aware of the basic facts underlying the lawsuit and not likely to abdicate his obligations to fellow class members." *Gordon v. Sonar Capital Mgmt. LLC*, 92 F. Supp. 3d 193, 200 (S.D.N.Y. 2015) (internal quotation marks omitted) (quoting *In re Monster Worldwide, Inc. Sec. Litig.*, 251 F.R.D. 132, 135 (S.D.N.Y. 2008)). This requirement is a modest one – "class representative status may be denied only 'where the class representatives have so little knowledge of and involvement in the class action that they would be unable or unwilling to protect the interests of the class against the possible competing interests of the attorneys.'" *Id.* (quoting *In re Monster Worldwide*, 251 F.R.D. at 135).

Finally, if certain members of the class are subject to unique defenses, the court must inquire as to whether those defenses "threaten to become the focus of the litigation." *Gordon v. Sonar Capital Mgmt. LLC*, 92 F. Supp. 3d 193, 205 (S.D.N.Y. 2015) (internal quotation marks omitted) (quoting *Romero v. Flaum Appetizing Corp.*, No. 07 Civ. 7222, 2011 WL 812157, at *3 (S.D.NY. Mar. 1, 2011)).

5. Ascertainability

In addition to the four factors enumerated in Rule 23(a), there is an "implied requirement that the membership of the class is identifiable and ascertainable." *Jankowski v. Castaldi*, No. 1 Civ. 0164 (SJF), 2006 WL 118973, at *5 (E.D.N.Y. Jan. 13, 2006) (quoting *In re Methyl Tertiary Butyl Ether Prods. Liab. Litig. (In re MTBE)*, 209 F.R.D. 323, 337 (S.D.N.Y. 2002)); *Noble v. 93 Univ. Place Corp.*, 224 F.R.D. 330, 337 (S.D.N.Y. 2004). A class is ascertainable if it is (1) sufficiently bounded so that it is feasible for the court to determine whether a particular individual is a member, and (2) defined by objective criteria that avoid a "mini-hearing on the merits of each case." *In re Petrobras Sec.*, 862 F.3d 250, 266 (2d Cir. 2017).

B. Rule 23(b)

If the class proponent satisfies each of the Rule 23(a) prerequisites, he must next demonstrate that at least one of the three requirements listed in subsection 23(b) is met. *Wal–Mart*, 564 U.S. at 345. Here, Plaintiffs seek certification under subsection 23(b)(3), which allows a claim for damages to proceed as a class if it is established that (1) common questions predominate over individual questions (the predominance requirement), and (2) the class action vehicle is superior to other possible methods of "fairly and efficiently adjudicating the controversy" (the superiority requirement). Fed. R. Civ. P. 23(b)(3).

1. Predominance

The predominance requirement, as a general matter, "tests whether proposed classes are sufficiently cohesive to warrant adjudication by representation." *In re Nassau Cty. Strip Search Cases*, 461 F.3d 219, 225 (2d Cir. 2006) (internal quotation marks and citation omitted). Even where Rule 23(a)'s commonality requirement is satisfied, predominance under Rule 23(b)(3) is not necessarily met because the latter requires considerably more. *Comcast Corp. v. Behrend*, 569 U.S. 27, 33 (2013). More than their mere presence, Rule 23(b)(3) requires that questions common to the class predominate over individual ones.

Determining whether a question is common or individual depends on the kind of proof that will be needed to resolve that question at trial. An individual question is one for which "members of a proposed class will need to present evidence that varies from member to member," while a common question is one for which "the same evidence will suffice for each member to make a prima facie showing [or] the issue is susceptible to generalized, class-wide proof." *Tyson Foods, Inc. v. Bouaphakeo*, 136 S.Ct. 1036, 1045 (2016). Plaintiffs are not, however, required to prove that these questions will be answered in their favor in order to certify a class under this provision. *See Amgen Inc. v. Conn. Ret. Plans & Tr. Funds*, 568 U.S. 455, 468 (2013).

Moreover, "individual questions need not be absent" in order to certify a class under Rule 23(b)(3); the text of Rule 23(b)(3) itself contemplates that such questions will be present. *Sykes*, 780 F.3d at 81. "The rule requires only that those questions not predominate over the common questions affecting the class as a whole." *Id.* (internal quotation marks omitted) (quoting *Messner v. Northshore Uni. HealthSystem*, 669 F.3d 802, 815 (7th Cir. 2012)). For example, if liability can be determined on a class-wide basis, common issues may predominate even in the

face of some individualized damages issues. *Sykes*, 780 F.3d at 81 (quoting *In re Visa Check*, 280 F.3d at 139).

2. Superiority

Finally, the district court must determine that "a class action is superior to other available methods for fairly and efficiently adjudicating the controversy." Fed. R. Civ. P. 23(b)(3). While, structurally, the four factors set forth in Rule 23(b)(3) govern both predominance and superiority, the Second Circuit has held that "they more clearly implicate" the latter. *Sykes*, 780 F.3d at 82. Accordingly, in determining whether the class action is a superior method, courts consider:

(A) the class members' interests in individually controlling the prosecution or defense of separate actions;

(B) the extent and nature of any litigation concerning the controversy already begun by or against class members;

(C) the desirability or undesirability of concentrating the litigation of the claims in the particular forum; and

(D) the likely difficulties in managing a class action.

Fed. R. Civ. P. 23(b)(3). Manageability is, by far, the most critical factor in the superiority determination. *Id.*

Analysis

Plaintiffs seek to certify a class comprising "All persons or entities in the United States and its territories who purchased branded Namenda IR 5 or 10 mg tablets, and/or generic Namenda IR 5 or 10 mg tablets (including an authorized generic), and/or branded Namenda XR capsules, directly from Forest or its successors in interest, Actavis and Allergan, and/or from any generic manufacturer at any time during the period from June 2012 until September 30, 2015." (Pls.' Mot. for Class Certification, Ex. 1, Dkt. No. 400 ("Class Cert. Mot.").)

The proposed class consists of 62 members. (Pls.' Reply Mem. of Law in Supp. of Direct Purchaser Class Pls.' Mot. for Class Certification at 2, Dkt. No. 421 ("Pls.' Reply")). All are

major pharmacy retailers (like CVS or Walgreens) or wholesalers who sell to major pharmacy retailers. They purchase Namenda or Namenda-generics for resale to pharmacies and/or consumer patients. (Lamb Rep. ¶ 42.)

At the outset, I reject Defendants' argument that Smith and RDC are inadequate class representatives because they lack sufficient knowledge and involvement in the case, and have abdicated all control to counsel. (Defs.' Opp'n to Direct Purchaser Pls.' Mot. for Class Certification at 20, Dkt. No. 412 ("Defs.' Opp'n").) Both RDC and Smith have indicated their knowledge of and interest in pursuing the claims of the class. (Hamburger Decl. Ex. 14, Dkt. No. 410 ("Doud Dep. Tr.") at 10:25 – 11:21, 14:6 – 24, 155:20 – 23, 180:1 – 3; Hamburger Decl. Ex. 15, Dkt. No. 410 ("Benton Dep. Tr.") at 25:8 – 23, 46:15 – 17, 283:14 – 284:7, 295:9 – 24.)

Defendants' remaining inadequacy arguments pertaining to specific conflicts will be addressed in the discussions of the relevant subgroup.

The proposed class can be broken down into 5 subgroups: (1) Forest Direct Customers; (2) Generic Purchasers (with a sub-subgroup of Non-Forest Generic Purchasers); (3) Corporate Subsidiaries; and (4) allegedly uninjured entities. As Plaintiffs have removed DIK Drug, First Veterinary Supply, and H.D. Smith Wholesale from the revised list of proposed members, they are not included in the following discussion.

Forest Direct Customers. 19 entities (including named Plaintiffs Smith and RDC) are direct customers of Defendants ("Forest Direct Customers"). These entities purchased branded Namenda IR and XR from Defendants, and all also purchased the generic. (Dkt. No. 552.) The members of this subgroup assert both "reverse payment" and "hard switch" claims. They are Amerisource Bergen; Anda; Capital Wholesale; Cardinal Health; Dakota Drug; Drogueria Betances; Drogueria Cesar Castillo; Frank W. Kerr Inc.; HD Smith LLC; Louisiana Wholesale

Drug; McKesson; Miami Luken; Morris & Dickson; North Carolina Mutual Wholesale Drug; PBA Health; Prescription Supply Inc.; RDC; Smith; and Value Drug.

With respect to this subgroup, Defendants argue that Smith and RDC are inadequate representatives because 3 members are subject to a unique defense that other members have no interest in defending against. (Defs.' Opp'n at 21.) They argue that Amerisource Bergen, Cardinal, and McKesson ("the Big Three"), are subject to a "generic bypass" defense insofar as "they may have benefitted from Forest's conduct because of the tendency for generic companies to bypass wholesalers and sell directly to retailers." (*Id.* at 21.) The question here is whether the generic-bypass defense "threaten[s] to become the focus of the litigation." *Gordon*, 92 F. Supp. 3d at 205 (internal quotation marks omitted) (quoting *Romero*, 2011 WL 812157, at *3).

These arguments aside, Defendants concede that these 19 entities would be properly included in any class that might be certified. They urge, however, that a class of 19 members is not sufficiently numerous to warrant certification.

As to the other 43 members of the proposed class, Forest objects, on multiple grounds, to their inclusion in a certified class.

Generic Purchaser Group. 31 entities purchased only generic memantine ("the Generic Purchaser Group"). They are Albertsons LLC, American Health Packaging, Associated Pharmacies, Auburn Pharmaceutical; Bloodworth Wholesale Drugs; Blupax Pharmaceuticals, LLC; CVS Caremark; Drugs Unlimited, Inc.; Express Scripts Inc.; Genetco Inc.; Hannaford Brothers; HC Pharmacy Central Inc.; Healthsource Distributors, LLC; Humana Inc.; Independent Pharmacy Cooperative; Kaiser Permanente; Keysource Medical, Inc.; Major Pharmaceuticals/Rugby Laboratories; Masters Pharmaceutical Inc.; Medco Health Solutions Inc.; Meijer, Inc; OptumRx Inc.; Peytons; Quest Pharmaceuticals, Inc.; Richie Pharmaceutical

Company; Rx Outreach; Supervalu Inc.; Tel Drug of PA LLC; TopRx LLC; Walmart; and Winn Dixie Logistics Inc.

Defendants argue that the Generic Purchaser Group was not comprehended within the original class definition proposed in the complaint and that should not be added into the mix now. As to all thirty-one members, Defendants argue that these members' claims are not typical of the named Plaintiffs' claims (or of the claims of the Forest Direct Customers) and either lack common questions with the hard switch claims asserted by the Forest Direct Customers or any common claims do not meet the predominance standard of Rule 23(b)(3); and that the named Plaintiffs have no incentive to represent the interests of this group as a result. (Defs.' Opp'n at 10 – 12.)

In addition to the objections described above, Defendants also argue that 30 members of the Generic Purchaser Group lack antitrust standing under *Illinois Brick*, 431 U.S. 720 (1977), because only one entity – Meijer, Inc. – purchased generic memantine directly from Forest. (Dkt. No. 552.) All other entities purchased generics from entities other than Forest and Mylan during the last two and one half months of the class period. I will call them the "Non-Forest Generic Purchaser Group."

Corporate Subsidiaries. Defendants object to the inclusion of 4 entities on the basis that class membership should be limited to the common parent of corporate family members – Bellco, Burlington Drug, The Harvard Group, and Valley Wholesale. (Defs.' Opp'n at 13 – 14.)

Allegedly Uninjured Members. Defendants argue that 9 entities (including The Harvard Group from the previous list) must be excluded because they were not injured.

Publix, HE Butt, Kerr Drug, and Bartell allegedly suffered no injury from the purported scheme because they never bought Namenda IR and stopped buying Namenda XR before the hard switch announcement. (*Id.* at 12.)

DMS allegedly suffered no injury from the purported scheme because it purchased neither Namenda IR nor Namenda XR until after generic entry. (*Id.* at 12 – 13.)

Discount Drug Mart, Drogueria Central, and The Harvard Drug Group allegedly suffered no injury from the hard switch because they never purchased Namenda XR at all. (*Id.* at 13.)

Finally, Bartell, Drogueria Central, Kerr Drug, and Kroger allegedly were not injured by the scheme because they purchased only branded Namenda, even following generic entry. (*Id.* at 13.) (Bartell, Kerr Drug, and Drogueria Central were already included in the previous lists.)

I will deal with Forest's objections group by group.

A. Corporate Subsidiaries

Defendants argue that class membership should be limited to the common parent of corporate family members and object to the inclusion of four entities they claim are owned by other members in the class. They are Bellco, Burlington Drug, The Harvard Group, and Valley Wholesale. Defendants assert that Bellco is owned by Amerisource Bergen; that Burlington Drug is owned by JM Smith Corporation; that The Harvard Group is owned by Cardinal; and that Valley Wholesale is owned by H.D. Smith LLC. (*Id.* at 13 – 14.)

Plaintiffs' Exhibit 9 addresses the corporate status of these entities. (Pls.' Ex. 9, Corporate Status of Certain Entities Listed in Manufacturer Transactional Data.)

The record indicates that Bellco is the wholly owned subsidiary of Amerisource Bergen Drug Corporation and has been incorporated in New York State since May 1960. (Pls.' Ex. 9-B.) Burlington Drug is a subsidiary of JM Smith Corporation, formed under the laws of Vermont in

January 1998. (Pls.' Ex. 9-C.) The Harvard Group is a majority-owned subsidiary of Cardinal, incorporated under the laws of Michigan in June 1997. (Pls.' Ex. 9-D.) And Valley Wholesale is a wholly-owned subsidiary of H.D. Smith, formed under the laws of Delaware in October 2012. (Pls.' Ex. 9-E.)

Plaintiffs argue that these subsidiaries are each entitled to a presumption of separateness from their parent corporations because the companies are separately incorporated, separately listed in the manufacturers' transactional data, and, most importantly, separately purchased (and were overcharged for) the product. (Pls.' Reply at 6.) In other words, related or not, each Class member that bought Namenda "suffered independent injury." (*Id.*)

I agree. Defendants do not dispute the fact that these entities each independently purchased Namenda products. I join with other courts that have considered this issue and have ruled that where there is distinct and separate injury, a corporate relationship with another class member does not defeat individual member status. *See, e.g.*, *In re Solodyn*, 2017 WL 4621777, at *4 (considering and rejecting this argument with respect to Valley Wholesale and H.D. Smith); *see also Am. Sales Co., LLC v. Pfizer, Inc.*, No. 14 Civ. 361, 2017 WL 3669604, at *8, 2017 U.S. Dist. LEXIS 137222, at *25 (E.D. Va. July 28, 2017) (allowing subsidiaries to vindicate their own antitrust injuries).

Plaintiffs provide sufficient evidence of separateness between these subsidiaries and their parent corporations. Any overcharges they paid for their own purchases of memantine are separately and distinctly applicable to them.

B. Miscellaneous Uninjured Members

Defendants' objections to the following entities are variations on a theme. At bottom, their arguments pertaining to Publix, HE Butt, Kerr Drug, Bartell, DMS, Drogueria Central,

Kroger, Discount Drug Mart, and The Harvard Group come down to the claim that, for one reason or another, these entities were not injured by Forest's alleged misconduct.

To frame the following discussion, it is instructive to review the proposed class members' alleged injuries. All members of the class claim that they were overcharged for their memantine requirements due to Forest's allegedly anticompetitive conduct.

With respect to the reverse payment claim, Plaintiffs allege that "all or nearly all" members of the class were overcharged. (Lamb Rep. ¶ 13-a.) They allege that any member who purchased Namenda IR, Namenda XR, and/or generic memantine hydrochloride paid higher prices than they otherwise would have had generic competition started earlier, "because they would have purchased (or purchased more) generic memantine at prices below branded Namenda and would have purchased the generic at lower prices." (*Id.*) In other words, Plaintiffs claim that the reverse payment injured any member who purchased Namenda IR, any member who purchased Namenda XR, and any member who purchased a generic alternative once it became available (from Forest or from a generic competitor).

With respect to the hard switch claim, Plaintiffs allege that "all or nearly all proposed Class members who purchased at least Namenda IR and XR, or XR" were overcharged. (Lamb Rep. ¶ 13-b.) In other words, Plaintiffs allege that any entity that purchased Namenda XR paid a higher price than they otherwise would have for the generic memantine they would have purchased in place of the more expensive brand name drug, and that they would have purchased more of that generic. (*Id.*)

Plaintiffs allege that the aggregate overcharges break down into two categories: "Brand-Generic" and "Generic-Generic." (*Id.* at ¶ 125.) The former relates to Forest's alleged foreclosure of class members' switching to generic memantine via both the reverse payment and

the hard switch strategy. Absent the reverse payment, Plaintiffs allege, a large volume of branded Namenda IR and Namenda XR purchases would have been replaced by generic memantine at a significantly reduced price. (*Id.*) "Brand-Generic" injuries thus include the higher prices paid by class members for the branded Namenda IR and XR they actually bought instead of the lower-priced generic alternative they would have bought absent the reverse payment and the hard switch strategy. (*Id.*)

"Generic-Generic" overcharges relate to the higher prices that class members paid for the generic alternatives they actually bought. (*Id.* at ¶ 126.) The reverse payment led to such overcharges because it delayed generic entry and "prices for generic drugs tend to decline over time as generic manufacturers compete against each other." (*Id.*) The hard switch strategy led to Generic-Generic overcharges because it shifted the Namenda IR prescription base to Namenda XR before generics had the chance to compete for Namenda IR business. (*Id.* at ¶ 65.) In light of the 89.9% substitution rate of generic memantine for brand Namenda IR over the three months following generic entry, Dr. Lamb concludes that generic entry would have affected a larger base of IR prescriptions absent the hard switch. (*Id.* at ¶ 81.) Plaintiffs submit that generic memantine purchasers paid higher prices because this suppressed generic sales and their attendant savings. (*Id.* at ¶ 65.) The Generic-Generic category would apply to any member who purchased generic memantine, whether they previously purchased branded Namenda products or not.

Moving to Defendants' specific objections, they first argue that Publix, HE Butt, Kerr Drug, and Bartell were not injured because they never bought Namenda IR and stopped buying Namenda XR before the hard switch announcement. (Defs.' Opp'n at 12.) These entities were injured under the Brand-Generic theory described above insofar as Plaintiffs allege that

Namenda XR purchases would have been replaced by generic memantine at a significantly reduced price.

Publix and HE Butt were also injured to the extent they purchased generic memantine. The record indicates that Kerr Drug and Bartell never purchased generic memantine. (*See* Hamburger Decl. Ex. 13, Dkt. No. 410 (Expert Report of Pierre-Yves Cremieux ("Cremieux Rep.")), at ¶ 63 (Ex. 1.2, Summary of Findings: Reverse Payment).)

Defendants argue that DMS could not have been injured by the alleged scheme because it did not make any purchases of Namenda IR or Namenda XR until after generic entry." (Defs.' Opp'n at 13.) To the extent Plaintiffs allege that DMS purchased generic memantine during the class period, DMS suffered injury in the form of Generic-Generic overcharges.

Defendants argue that Bartell, Drogueria Central, Kerr Drug, and Kroger should be excluded because they did not buy generic memantine, even after it became available following generic entry. They submit that there is no basis to assume that such brand-only purchasers "would have purchased generic Namenda IR in the but-for world." (*Id.* at 13.)

I understand Defendants' argument that the decision to continue buying branded Namenda products, even after generics entered the market, casts doubt on the fact that these entities would have purchased the generic earlier had it been available to them. But Defendants are not entitled to the benefit of that doubt when the very reason we cannot know the answer to that question is because of their alleged wrongdoing. *See In re DDAVP*, 585 F.3d at 689.

Defendants argue that Discount Drug Mart, Drogueria Central, and The Harvard Group "could not have been injured by the hard switch" because they never purchased Namenda XR or stopped purchasing Namenda XR before the February 2014 announcement, and should therefore be excluded with respect to the hard switch claim. (Defs.' Opp'n at 13.)

That these entities never purchased Namenda XR does not establish that they were uninjured by the hard switch. If the jury finds Forest liable on Plaintiffs' theory of liability, these members were injured insofar as the hard switch strategy shifted the Namenda IR prescription base, thereby suppressing generic sales and their attendant savings. In the case of Discount Drug Mart, the question of whether its purchases were "due to" the hard switch strategy is a question for the trier of fact, given the evidence of Defendants' pre-announcement communications with key stakeholders and customers regarding the launch of Namenda XR and withdrawal of Namenda IR.

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That brings Plaintiffs to a total proposed class of 31 members, which is still below the commonly accepted threshold of 40 members needed to warrant class certification.

And so we turn to the largest and most complicated group of potential class members – the one as to which Forest levels the most objections. If they can be included in the class, it will easily exceed the 40 member threshold. If they cannot, certification becomes more problematic.

C. Generic Purchaser Group

This category includes members who purchased generic memantine hydrochloride. They are Albertsons LLC; American Health Packaging; Associated Pharmacies; Auburn Pharmaceutical; Bloodworth Wholesale Drugs; Blupax Pharmaceuticals, LLC; CVS Caremark; Drugs Unlimited, Inc.; Express Scripts Inc.; Genetco Inc.; Hannaford Brothers; HC Pharmacy Central Inc.; Healthsource Distributors, LLC; Humana, Inc.; Independent Pharmacy Cooperative; Kaiser Permanente; Keysource Medical, Inc.; Major Pharmaceuticals/Rugby Lab; Masters Pharmaceutical Inc.; Medco Health Solutions Inc.; Meijer Inc.; Optumrx Inc.; Peytons;

Quest Pharmaceuticals, Inc.; Richie Pharmaceutical Company; RX Outreach; Supervalu Inc.; Tel Drug of PA LLC Joann Christens; Top RX LLC; Walmart; and Winn Dixie Logistics Inc.

Forest objects to the inclusion of the entire Generic Purchaser Group because generic purchasers were not included in the original class definition proposed in the complaint. It also argues that their claims are not typical of Forest Direct Customers, and that their claims either lack common questions with the Forest Direct Customers' hard switch claim, or any common issues do not predominate. Forest argues that named Plaintiffs' interests are not aligned with the Generic Purchaser Group as a result. (*Id.* at 10 – 11.)

Finally, because all but one Generic Purchaser – Meijer, Inc. – purchased memantine from Forest's generic competitors, not from Forest itself, Forest objects to the Non-Forest Generic Purchasers on the further ground that they lack antitrust standing under *Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1977). (Defs.' Opp'n at 11 – 12.)

1. Expanded Class Definition

Defendants are correct that the inclusion of the Generic Purchaser Group expands upon the definition found in Plaintiffs' complaint, which proposed a class consisting only of members who purchased Namenda IR or XR *directly* from Forest. (*See* Am. Compl. ¶ 193.) They are wrong, however, when they argue Plaintiffs "were obligated to seek leave to amend the Complaint well before fact discovery closed." (Defs.' Opp'n at 11.)

It is well-established that a certifying court "is not bound by the class definition proposed in the complaint." *Robidoux v. Celani*, 987 F.2d 931, 937 (2d Cir. 1993). However, this principle is customarily cited as support for the court's ability to narrow a proposed class. *See, e.g.*, *Lundquist v. Sec. Pac. Auto. Fin. Servs. Corp.*, 993 F.2d 11, 14 (2d Cir. 1993); *Madden v. Midland Funding, LLC*, 237 F. Supp. 3d 130, 153 (S.D.N.Y. 2017); *Flores v. Anjost Corp.*, 284

F.R.D. 112, 125 (S.D.N.Y. 2012); *Poddar v. State Bank of India*, 235 F.R.D. 592, 595 (S.D.N.Y. 2006). Far fewer cases support the converse proposition that the court may approve the expansion of the class as it was defined in the complaint. Plaintiffs cite three cases to this end, two of which are instructive here – *Menking ex rel. Menking v. Daines*, 287 F.R.D. 174 (S.D.N.Y. 2012) and *McCarthy v. Paine Webber Grp., Inc.*, 164 F.R.D. 309 (D. Conn. 1995).

In *Menking*, 287 F.R.D. at 181, even though the plaintiff originally sought certification of a *citywide* class in her complaint, the court approved a "new and expanded *statewide* definition for the proposed class," as requested by the plaintiff in her motion for class certification "based on evidence obtained in discovery." In *McCarthy*, 164 F.R.D. at 311, the plaintiff's motion for class certification proposed a class comprising all persons who owned limited partnership interests in a particular entity. This was broader than the definition found in the complaint, which confined the class to persons who owned a limited partnership interest *during a particular time period*. *Id.* The court certified the broader class proposed in the motion for certification, noting that it was "not bound by the class definition proposed in the complaint." *Id.* (citing *Robidoux*, 987 F.2d at 937).

Menking and *McCarthy* demonstrate that a plaintiff's expansion of the class definition beyond that which was proposed in the complaint is not categorically improper. Rather, in both cases, the court went on to consider whether the newly proposed class members satisfied the substantive requirements of Rule 23(a).

Forest argues that, under *In re Aluminum Warehousing Antitrust Litig.*, No. 13-md-2481 (KBF), 2016 U.S. Dist. LEXIS 54643, at *32-33 (S.D.N.Y. Apr. 25, 2016), Plaintiffs must establish that there is good cause for expanding the class at this juncture because the time to add new members "has long passed." (Defs.' Opp'n at 11.) I disagree. Defendants' reliance on the

good cause standard discussed in *Aluminum Warehousing* is misplaced; there, the court was considering the plaintiffs' motion for leave to file a fifth amended complaint. *Aluminum Warehousing*, 2016 U.S. Dist. LEXIS 54643, at *21. This is a timely motion for class certification, not a belated motion for leave to file an amended complaint.

Moreover, Plaintiffs' proposed class definition does not raise the same notice and discovery issues present in *Aluminum Warehousing*. There, the proposed amendments would have added two new foreign defendants, "with respect to whom service would not be completed under the Hague Convention for at least several months," *id.* at *13; changed the plaintiffs' claims and proposed class definition "in the midst of class certification briefing in ways that could necessitate substantial new fact and expert discovery – including significant non-party and overseas discovery – that defendants could not have anticipated," *id.* at *13 – 14; and substantially broadened the scope of the proposed class and relevant transactions by including markets that the defendants had no "reason to address during the discovery period," *id.* at *14.

Plaintiffs here are not attempting to add any new defendants, let alone foreign parties. Nor are they attempting to broaden the class definition "in the midst of" class certification briefing – they included the expanded definition at the outset, in their initial motion for certification. (Class Cert. Mot., Ex. 1.)

Furthermore, Defendants had reason to anticipate during discovery any novel issues that the Generic Purchaser Group might introduce. While the Amended Complaint did not include the Generic Purchaser Group as members of the class, it specifically alleged that but for Defendants' anticompetitive conduct, members of the class would have paid less for memantine by "purchasing generic Namenda IR at lower prices sooner." (Am. Compl. ¶ 229.) It further alleged,

> Defendants' anticompetitive conduct, which delayed introduction into the United States marketplace of generic versions of Namenda IR, has caused plaintiff and the Class to pay

> more than they would have for memantine hydrochloride absent defendants' illegal conduct. . . . As more generic manufacturers enter the market, prices for generic versions of a drug predictably plunge even further due to competition among the generic manufacturers.

(*Id.* ¶¶ 226 – 27.) And indeed, Defendants' expert, Dr. Cremieux, addresses the claims of the Generic Purchaser Group throughout his report. (*See, e.g.*, Cremieux Rep. ¶ 63.)

Ultimately, consistent with the certifying court's broad discretion over class definition and obligation to reassess class rulings as the case develops, *Boucher v. Syracuse Univ.*, 164 F.3d 113, 118 (2d Cir. 1999) (quoting *Barnes v. Am. Tobacco Co.*, 161 F.3d 127, 140 (3d Cir. 1998)), I see no reason to disregard the class definition that Plaintiffs propose in their motion for class certification simply because it expands upon the definition found in the Amended Complaint.

2. Antitrust Standing

Defendants object to the inclusion of the Non-Forest Generic Purchasers in the class on the ground that they lack antitrust standing. Defendants rely on a line of cases beginning with *Illinois Brick*, to support their argument that "any purchases from a generic manufacturer (other than Mylan or Forest itself) could not form the basis of an antitrust claim." (Defs.' Opp'n at 12.)

However, these "direct-purchaser" cases are irrelevant because the Non-Forest Generic Purchasers are not *Illinois Brick* "indirect purchasers." Indirect purchasers are those who buy from the customers of a defendant – from people to whom the defendant sold product. *See Hanover Shoe v. United Shoe Mach. Corp.*, 392 U.S. 481, 492 – 94 (1968); *see also California v. ARC Am. Corp.*, 490 U.S. 93, 97 (1989); *Illinois Brick*, 431 U.S. at 724, 741; *Associated Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters*, 459 U.S. 519, 550 (1983). The Non-Forest Generic Purchasers bought from Forest's competitors. Vis-à-vis Forest, they are neither direct nor indirect; vis-à-vis the generic manufacturers from whom they bought their memantine, they are direct purchasers.

The Non-Forest Generic Purchasers have standing to bring antitrust claims against Forest if they (1) have suffered an antitrust injury "of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful," and (2) are proper plaintiffs in light of the four "efficient enforcer" factors. *In re DDAVP*, 585 F.3d at 688 (internal citations and quotation marks omitted) (quoting *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977); *Volvo N. Am. Corp. v. Men's Int'l Prof'l Tennis Council*, 857 F.2d 55, 66 (2d Cir. 1988)).

As to the first prong, the Non-Forest Generic Purchasers claim that they were overcharged for their purchases of generic memantine as a result of Forest's "two-part, allegedly anticompetitive and 'unlawful scheme to maintain a monopoly and to allocate the United States market for branded and generic versions of memantine hydrochloride." (Lamb Rep. ¶ 5.) Monopolist overcharges are "the classic antitrust injury." *Savory Pie Guy, LLC v. Comtec Indus., Ltd.*, No. 14 Civ. 7527 (VB), 2016 WL 7471340, at *12 (S.D.N.Y. Dec. 28, 2016); *see also Freeland v. AT & T Corp.*, 238 F.R.D. 130, 143 (S.D.N.Y. 2006). Paying higher prices for generic memantine is "inextricably intertwined" with the anticompetitive effects of Defendants' alleged conduct and thus "flows from that which makes [their] acts unlawful." *In re DDAVP*, 585 F.3d at 688 (quoting *Blue Shield of Va. V. McCready*, 457 U.S. 465, 484 (1982)).

As to the proper plaintiff prong, the Non-Forest Generic Purchasers satisfy the efficient enforcer criteria, which look to the (1) directness of the asserted injury, or causation; (2) self-interest of the class of persons to vindicate the public interest, or motivation; (3) speculativeness of the alleged injury; and (4) difficulty of identifying and apportioning damages so as to avoid duplicative recoveries. *Id.* at 688.

The Non-Forest Generic Purchasers' purported injuries are the direct result of the asserted antitrust violation – they allege they paid higher prices for generic memantine because Defendants intentionally restricted and manipulated generic competition.

They are also sufficiently motivated and well-positioned to vindicate the antitrust interests at play in this case. *See id.* at 689 (describing competitors as the most motivated antitrust plaintiffs); *see also In re Zinc Antitrust Litig.*, 155 F. Supp. 3d 337, 361 (S.D.N.Y. 2016) (describing competitors as the traditional plaintiff in antitrust cases).

Their claims support non-speculative damages, as they define damages by the difference between the prices they paid for generic memantine in the actual world and "those they would have paid in a world free of the alleged misconduct." *In re Zinc*, 155 F. Supp. 3d at 362 (finding injury sufficiently non-speculative for antitrust standing purposes where plaintiffs defined damages by the amount by which the price at issue was inflated). While it "may be difficult to account precisely for the likely effects of generic competition," the Court has "little doubt that those effects can be sufficiently estimated and measured here." *In re DDAVP*, 585 F.3d at 689. Plaintiffs have submitted expert reports and analysis that speak precisely and extensively to this issue.

For example, Dr. Lamb uses the nearly 95% discount of generic memantine and corresponding 89.9% adoption rate in the three months following generic entry to estimate the price a generic purchaser would have paid if generics had entered the market earlier. (Lamb Rep. at Fig. 3 (Brand and Generic Market Sales); Fig. 4 (Brand and Generic Namenda IR Average Price); Fig. 5 (Generic Namenda IR Average Price).)

Defendants' reliance on *In re Skelaxin (Metaxalone) Antitrust Litig.*, 2014 U.S. Dist. LEXIS 66707, at *29 – 41 (E.D. Tenn. May 15, 2014), is unpersuasive. While the alleged

antitrust conspiracy in that case largely tracks the facts of the scheme alleged here, I disagree with the court's conclusion that the relationship between fewer generic manufacturers and higher generic prices is "too speculative" to estimate the alleged overcharge. *Id.* at *36.

And finally, the circumstances of this case do not raise the same concerns of duplicative recovery as was true in *Illinois Brick* and the other "direct-purchaser" rule cases.

3. Adequacy of Named Plaintiffs

Defendants claim that RDC and Smith (both Forest Direct Customers) are inadequate representatives of a class including the Generic Purchaser Group because the majority of that group faces a unique standing hurdle, and no member of that group has an interest in the product-hopping claim. (Defs.' Opp'n at 21.)

I have already addressed and rejected Defendants' argument regarding the Non-Forest Generic Purchasers' antitrust standing.

I disagree with Defendants that the Generic Purchaser Group has no interest in the "hard switch" claim. Plaintiffs allege that the Generic Purchaser Group was impacted by the hard switch strategy because it led to higher generic prices. Dr. Lamb concluded that absent the hard switch strategy, and given the 89.9% substitution of generic memantine for brand Namenda in the three months following generic entry, generic entry would have affected a larger base of IR prescriptions and led to increased generic memantine purchases and savings. (Lamb Rep. ¶ 81.)

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With the Generic Purchaser Group included, the class comprises 62 members and the numerosity requirement is presumptively satisfied. *Ramirez v. Riverbay Corp.*, 39 F. Supp. 3d 354, 362 (S.D.N.Y. 2014) (citing *Consol. Rail Corp. v. Town of Hyde Park*, 47 F.3d 473, 483 (2d Cir. 1995)).

The various other factors in the numerosity analysis also weigh in favor of certification. The class members in this case are spread across the country; a fair number are located on the East Coast, others on the West, and still others in Puerto Rico. (Lamb Reply Rep. at Fig. 2.) Their disparate locations constitutes both a significant and practical difficulty to joinder. Individual suits filed in each of these locations would also impose an unnecessary and substantial burden on the judicial system.

There is also evidence that a number of the potential class members are small wholesalers that lack the financial resources to bring individual actions. (Lamb Rep. ¶ 42.) While all members might have the same incentive to bring individual actions, they do not have the same ability to do so.

D. Typicality, Commonality, and Predominance

Defendants' objections to the various subgroups addressed above are, in reality, arguments about typicality, commonality, and predominance. These analyses share a similar focus – they test whether the class is "sufficiently cohesive to warrant adjudication by representation," *In re Nassau Cty. Strip Search Cases*, 461 F.3d 219, 225 (2d Cir. 2006) (internal quotation marks and citation omitted) (quoting *In re Visa Check*, 280 F.3d at 136).

Defendants argue that RDC and Smith's claims are not typical of a class that includes (1) three national wholesalers, AmerisourceBergen, McKesson, and Cardinal Health, or (2) the Generic Purchaser Group. (Defs.' Opp'n at 19 – 20.) As to the inclusion of AmerisourceBergen, McKesson, and Cardinal Health, Defendants argue that because "the Big Three" are large national wholesalers, they are in a fundamentally different position than RDC and Smith and enjoy significantly more negotiating power and leverage with suppliers like Forest. (*Id.* at 19.) The size of these entities, however, does not change the fact that their claims arise from the same

course of conduct alleged by all class members – the reverse payment and the hard switch strategy. As members who purchased both branded Namenda products and the generic alternative, these entities advance legal arguments identical to members in the Forest Direct Customer subgroup.

It is a more complicated question whether common questions can be said to exist, and indeed, to predominate, when the class includes all subgroups. As commonality is subsumed under the more demanding predominance requirement, *Dial*, 314 F.R.D. at 113, I proceed directly to the Rule 23(b)(3) analysis, which imposes upon the court the "duty to take a 'close look' at whether common questions predominate over individual ones." *Comcast*, 569 U.S. at 34. That discussion also addresses the typicality argument Defendants raise with respect to the Generic Purchaser Group.

The parties agree that Plaintiffs must show that three elements are capable of proof at trial through evidence common to the class: (1) a violation of antitrust law; (2) injury and causation; and (3) damages. *See Fleischman v. Albany Med. Ctr.*, 639 F.3d 28, 29 – 30 (2d Cir. 2011).

Liability. Plaintiffs claim that "the proof necessary to establish Defendants' wrongdoing will not vary Class member-by-Class member." (Mem. in Support of Direct Purchaser Class Pls.' Mot. for Class Certification at 17.) They argue that the reverse payment with Mylan presents "solely" common issues, and that the product-hop theory presents "predominantly" common issues. (*Id.* at 17.)

As to liability, I agree that common questions predominate over the class, including the generic-only purchasers. If each Class members were to pursue this theory individually, "each would have to prove the same course of conduct, using the same documents and witnesses." (*Id.*

at 17.) To establish the reverse payment claim, for example, all members will need to present evidence of the agreement and its terms. Similarly, to establish the hard switch claim, members have indicated that they will offer evidence of pre-announcement communications with key stakeholders and customers regarding the forthcoming launch of Namenda XR and withdrawal of Namenda IR; evidence of the announcement itself; evidence pertaining to Judge Sweet's December 15, 2014 order; and evidence related to the aftermath of that order, including Forest's communications regarding its intention to challenge Judge Sweet's order in the Court of Appeals.

Injury. Plaintiffs allege that 58 of the 62 members in the proposed class were impacted by the Brand-Generic and/or the Generic-Generic overcharge because they either switched from branded Namenda to the generic alternative once it became available, or just bought the generic. (Pls.' Reply at 2.) (Only 4 purchasers – Bartell, Drogueria Central, Kerr Drug, and Kroger – continued to buy branded Namenda following generic entry.) They claim that the brand-to-generic purchasers suffered Brand-Generic overcharges during the time they were purchasing branded Namenda products and also suffered Generic-Generic overcharges once they switched to the generic alternative. (Lamb Rep. ¶ 126.)

Common questions predominate as to injury. First and foremost, at trial, all but 4 members of the class would need to prove they were injured by the Generic-Generic overcharge – that, but for Defendants' conduct, "generic prices by July 2015 would have been lower." (Pls.' Reply at 4.) This is but one aspect of the injury suffered by the 27 customers who allege they also paid higher prices for the branded Namenda they actually purchased. For the remaining 31 members, the Generic Purchaser Group, this is the ultimate question with respect to injury.

Therefore, 58 of the 62 members (just about 94% of the class) allege they were injured by paying higher prices for the generic memantine they actually purchased.

This issue is susceptible to generalized, class-wide proof. As Defendants point out, Plaintiffs' proof of injury will necessarily be intertwined with proof of damages. (Defs.' Opp'n at 23.) In other words, proving that they were injured will be bound up with proving the extent to which Plaintiffs were injured. *McLaughlin v. Am. Tobacco Co.*, 522 F.3d 215, 227 (2d Cir. 2008).

The 58 members claiming Generic-Generic damages all need to establish that the less expensive generics would have entered the market earlier; that generic prices would have continued to fall over time as more generic manufacturers competed; and that they would have paid less for their actual generic purchases. They will also need to show that the hard switch strategy further suppressed generic competition (and therefore savings) by shifting the Namenda IR prescription base to Namenda XR before generic entry.

All class members indicate that they plan to rely on Dr. Lamb's analysis of antitrust injury and damages, which, in turn, is based on three categories of proof that he states is "common to the proposed Class as a whole rather than specific to individual members." (Lamb Rep. ¶ 67.) His conclusions are based on: (1) peer-reviewed economic and government research showing that generics typically enter the market at lower prices than their brand name counterparts and capture a significant share of the total unit sales for that drug; (2) Forest's internal forecasts of the impact that generic competition would have on the memantine market; and (3) data on the actual sales volumes and prices of Namenda IR, Namenda XR, and generic memantine (which shows a 95% price discount for the generic and an 89.9% substitution rate by September 2015), derived from IMS Health's NSP database. (*Id.* at ¶¶ 68 – 85.)

They also intend to rely on his analysis of the impact that the hard switch had on generic competition. (*Id.* at ¶ 119.) For example, while Forest lost 96.5% of Namenda IR sales within six months of generic entry, it retained significant sales of branded Namenda because over 50% of existing Namenda patients had already switched to Namenda XR – "far more than the approximately 30 percent that [Forest's] own planning indicated would be possible in the absence of a hard switch." (*Id.* at ¶ 87; *see also* Pls.' Reply at 16.) This analysis again relies in part on internal forecasts, including Forest's comparison of its loss of exclusivity over Namenda IR with the Hard Switch strategy and without it. Other common evidence includes communications from Forest to various stakeholders (physicians, caregivers, pharmacies) and customers regarding Forest's "Namenda IR to XR Conversion Project" and informing them of the withdrawal of Namenda IR "immediately and for the next six months." (Pls.' Reply at 11; Lamb Rep. ¶ 98.) All members indicate they will rely on this evidence at trial to prove that, while Namenda IR was never fully removed from the market, due to Judge Sweet's December 15, 2014 order, "this communications strategy was successful for Forest in triggering wide-spread conversion to Namenda XR." (Lamb Rep. ¶ 63.)

While the Generic Purchaser Group will not (and could not) prove that they were injured by any Brand-Generic overcharges, determining Brand-Generic damages does not overwhelm the predominantly common issues that govern the class. To determine Brand-Generic damages, Plaintiffs indicate that they will rely on some of the same evidence discussed in connection with the Generic-Generic damages. To determine Brand-Generic damages, Dr. Lamb used the NSP database to calculate both "the price differential between the actual average Namenda IR and Namenda XR prices and *but-for average monthly generic memantine hydrochloride prices*" and "the price differential between the actual average Namenda XR monthly prices and *but-for*

average monthly generic memantine hydrochloride prices." (*Id.* at ¶ 125 (emphasis added).) For both Brand-Generic and Generic-Generic damages, class members will need to establish the price of average monthly generic memantine but for Defendant's alleged misconduct. The additional factor in the Brand-Generic computation is the actual average monthly price of Namenda IR and Namenda XR, which is a far less complicated question. It does not overwhelm the predominating issues in this case.

Damages. Defendants argue that Dr. Lamb's models do not provide a sufficient method of measuring class-wide damages. It is not enough that Plaintiffs supply a method to measure and quantify damages on a class-wide basis; the court must be satisfied that "the methodology [is] a just and reasonable inference," and is not speculative. *Comcast Corp.*, 569 U.S. at 35. Defendants argue that Plaintiffs cannot meet this burden.

Plaintiffs must demonstrate that Dr. Lamb's methodology identifies only damages that result from Defendants' wrong – *i.e.*, it must isolate damages that inhere from a valid theory of antitrust impact from those that do not. In *Comcast*, 569 U.S. at 36, the Supreme Court held that the plaintiffs' proposed methodology failed to do so where their expert's model assumed the validity of all four alleged theories of antitrust impact, but the district court credited only one of those theories. The expert's testimony confirmed that his model "calculated damages resulting from 'the alleged anticompetitive as a whole' and did not attribute damages to any one particular theory." *Id.*

Dr. Lamb's methodology in this case does not suffer from the same infirmity identified in *Comcast*, 569 U.S. at 37. Dr. Lamb's methodology would in fact be able "to bridge the differences between supra-competitive prices in general and supra-competitive prices attributable" to each step of the alleged two-part maneuver that Plaintiffs allege in this case.

Comcast, 569 U.S. at 38. In *Comcast*, the plaintiffs' expert established a single "'but-for' baseline – a figure that would show what the competitive prices would have been if there had been *no* antitrust violations." *Id.* By contrast, Dr. Lamb has provided multiple models that account for different "but-for" scenarios. (Lamb Rep. ¶ 121 ("I have applied benchmark methodologies to measure damages associated with each of the two components of the alleged misconduct.").)

In his report, Dr. Lamb discusses the measurement of class-wide damages in both the "No Reverse-Payment But-For World," *id.* at ¶¶ 139 – 42, and the "No Hard Switch But-For World." (*Id.* at ¶¶ 158 – 60.) These various models allowed Dr. Lamb to isolate and analyze damages arising from each aspect of Forest's alleged anticompetitive conduct. (*Id.* at ¶¶ 141, 158.); *see also In re Solodyn*, 2017 WL 4621777, at *10 (approving the plaintiffs' expert's model which provided for twelve but-for scenarios, "contemplating the different possible points of sustained generic entry absent the [alleged conduct] and the varying competitive conditions that would have followed").

Defendants challenge the ability of Dr. Lamb's hard switch and reverse payment models to measure classwide damages. Their overarching objection is that Dr. Lamb's models assume the injury that they purport to prove. To the extent I have addressed these objections in connection with Defendants' motion to exclude Dr. Lamb as an expert, I will not readdress them here.

1. Hard Switch Methodology

To calculate hard switch damages, Dr. Lamb started with actual Namenda XR sales volume over the class period. (Lamb Rep. ¶ 146.) He subtracted from that number the estimated sales volume of Namenda XR that Forest predicted would occur if it did not commence the hard

switch (lawful conversion). (*Id.*) The difference between those figures, Dr. Lamb concludes, is attributable to the hard switch. (Pls.' Reply at 11; Lamb Rep. ¶ 146.) He performed a structural break / statistical significance test to confirm this conclusion. He then used this figure (the difference between actual and but-for Namenda XR sales) to calculate the price that class members who purchased Namenda XR would have paid for generic memantine instead of purchasing Namenda XR. (Lamb Rep. ¶ 147.)

Defendants argue that Dr. Lamb's hard switch model, including the structural break test that purports to confirm his conclusion, fail to prove causation. (Defs.' Opp'n at 31.) Without proving that proposed class members' Namenda XR purchases were made because of the hard switch, Defendants claim that Dr. Lamb's models fail to show that members were injured. This is more or less the same argument made in Defendants' motion to exclude Dr. Lamb's expert testimony. Defendants again argue that Dr. Lamb's hard switch methodology fails to show causation because it includes market-wide, rather than purchaser-specific information, and imposes a 30% threshold of lawful Namenda XR adoption. I remain unpersuaded.

In the class certification context, Defendants emphasize that market-wide data cannot establish causation because it does not account for patient and physician prescribing preferences, which would require individualized proof. I reiterate what I said in my discussion of Defendants' motion to exclude Dr. Lamb's expert testimony – Plaintiffs' allegation is that Forest worked to ensure a "'forced switch' whereby physicians and patients would have little choice but to switch to Namenda XR." (Lamb Rep. ¶ 89.) They allege that limiting patient and physician preferences was precisely the point of "discontinu[ing] or dramatically restrict[ing] the supply of Namenda IR several months before the availability of generic memantine." (*Id.*)

In this case, the idiosyncrasies of patient preferences do not require a degree of individualized proof that makes class certification inappropriate. Defendants' reliance on *McLaughlin* is undermined by the fact that the proposed members were not individual consumers – a fact of fundamental importance to the court's decision in that case. *See, e.g.*, *McLaughlin*, 522 F.3d at 224; *id.* at 229; *id.* at 225 n.7. Here, proposed members are not patients; they are "wholesalers and other direct purchasers." (Pls.' Reply at 14.) Forest does not contest the fact that it "deals with wholesalers, not patients." (*Id.*) I agree with those courts that have rejected the argument that a class comprising direct purchasers must show that individual patient decisions were the result of the defendant's alleged conduct. *See In re Warfarin Sodium Antitrust Litig.*, 391 F.3d 516, 528 –29 (3d Cir. 2004) (plaintiffs' allegation of overpayment for drug was "purely an economic injury" supporting a finding of commonality and predominance); *In re Solodyn*, 2017 WL 4621777, at *10; *Teva Pharm. USA, Inc. v. Abbott Labs.*, 252 F.R.D. 213, 229 (D. Del. 2008).

As to the 30% lawful adoption rate imposed in Dr. Lamb's model, I have already addressed the propriety of this figure in response to Defendants' motion to exclude Dr. Lamb and Dr. Berndt's use of forecast averages in their respective analyses. This threshold was derived from Forest's own documents and forecasts, which compared hard switch and soft switch scenarios, as well as internal high-level analysis of how these forecasts impacted potential Namenda XR conversion rates. These forecasts were not, as Defendants state, "cherry-picked." Dr. Lamb relied on forecasts that were (1) "closest in time to Forest's decision to enact the hard switch, after Forest had market experience with Namenda XR and predicted generic entry in July 2015 (when it actually occurred), and thus incorporated the best analysis Forest had at the time";

and (2) "consistent with Forest's actual conversion rate through January 2014, before the switch announcement." (Pls.' Reply at 18.)

In any event, disputes over which forecasts are the appropriate forecasts do not discredit Dr. Lamb's methodology at the class certification stage. It is for the jury to decide whether the his opinions are persuasive. *See In re Solodyn*, 2017 WL 4621777, at *10.

It is also worth noting that, when estimating the adoption rate of Namenda XR absent the hard switch, it stands to reason that Forest took factors such as patient and physician prescribing preferences into account. As Dr. Lamb indicates, Forest's Namenda XR conversion rates were both thorough and kept up to date, with multiple forecasts being created in the space of a few weeks. (Lamb Rep. ¶ 151.)

Defendants raise the additional argument that Dr. Lamb dismisses the impact of Judge Sweet's injunction and Forest's "campaign to comply with it." (Defs.' Opp'n at 30.) Dr. Lamb considered this possibility at length. He concluded, however, that the injunction "was unlikely to have eliminated the anticompetitive effects of Forest's Hard Switch strategy." (Pls.' Reply at 12; Lamb Reply Rep. ¶ 69 – 75.) He reached this conclusion based on two categories of evidence.

First, when Forest informed customers of the injunction, it indicated that it was "appealing" the order and intended to "convince the higher court that, in fact, the lower court's decision was in error." (Opper Decl. Ex. 13, Dkt. No. 421 ("Cremieux Dep. Tr.") at 13:18 – 21.) After the Second Circuit upheld the injunction, Forest continued to challenge it through November 2015, and communicated this to its customers. (Pls.' Reply at 12; Lamb Rep. ¶ 114.) Plaintiffs' argue that the effects of the hard switch continued because, contrary to Forest's alleged campaign to comply with the injunction, Forest "intentionally sowed doubt" as to whether it would stand. (Pls.' Reply at 12.) This is supported by evidence cited in Dr. Lamb's

report that "physicians were often hesitant to prescribe Namenda IR following the Court's injunction." (Lamb Rep. ¶ 116.)

Second, Dr. Lamb reviewed evidence indicating the difficulty of transitioning patients back to Namenda IR once they had switched to Namenda XR. This includes evidence that physicians were hesitant to prescribe, and pharmacies and health plans no longer covered, Namenda IR following the injunction. (*Id.* at ¶ 118.) Plaintiffs thus argue that, regardless of the injunction, "the marketplace, once shifted, would be slow to revert back to IR." (Pls.' Reply at 12.)

2. Reverse Payment Methodology

Because Dr. Lamb's reverse payment model incorporates hard switch damages, Defendants argue that it suffers from the same flaws described above. That discussion applies with respect to those objections.

Defendants claim that the reverse payment model suffers from additional flaws. They argue both that it is "premised on assumptions regarding generic pricing and penetration that are untethered from the actual world and sound economic theory," and that it allocates damages on the assumption that each member was injured by the reverse payment and the hard switch strategy. (Defs.' Opp'n at 31.)

The first objection is without merit. I disagree that Dr. Lamb's methodology in connection with the reverse payment model is divorced from sound economic theory. Dr. Lamb explains that he used a "benchmark analysis" to measure the overcharge resulting from the reverse payment, which "has been widely used for many years in calculating damages that arise from anticompetitive conduct of the sort alleged in this case." (Lamb Rep. ¶ 131.) I have reviewed Dr. Lamb's qualifications and the soundness of his expert testimony in the motion to

exclude that testimony. To the extent that Forest disagrees with the generic entry date and number of generics that Dr. Lamb uses in his calculations, they are free to explore those issues on cross-examination.

The second part of Defendants' challenge to the reverse payment model speaks to their previous objections about which members were and were not injured. For example, they state, "Dr. Lamb's allocation awards damages for the hard switch to entities that never even purchased Namenda XR," and "allocates damages and assumes injury to entities that never purchased generic IR and thus could not have been injured by any of Forest's conduct." (Defs.' Opp'n at 32.) These are arguments about Plaintiffs' theory of injury, not about Dr. Lamb's methodology. I have already addressed these arguments in the discussion of which members could and could not be included in the class.

E. Superiority

Finally, a class action is superior to other available methods for fairly and efficiently adjudicating this controversy, as required under Rule 23(b)(3).

The first consideration under Rule 23(b)(3)(A) is whether the class members have an interest in controlling the prosecution of separate actions. There is no evidence that any of the direct purchasers would prefer to control the prosecution of their claims through separate lawsuits. On the contrary, Plaintiffs submit that many members of the class would forego their claims altogether rather than pursue them individually because, as small wholesalers, they "lack the resources to bring complex, expert-intensive antitrust suits on their own." (Class Cert. Mot. at 9.) The Court is not aware of any other litigation concerning this controversy by or against the direct purchaser class members. *See* Fed. R. Civ. P. 23(b)(3)(B).

Class treatment is appropriate in such "negative value cases," in which each class members' interest in the litigation is less than the cost to maintain an individual action. *Royal Park Invs. SA/NV v. Wells Fargo Bank, N.A.*, No. 14 Civ. 9764 (KPF), 2018 WL 739580, *16 (S.D.N.Y. Jan. 10, 2018) (citing *Noble*, 224 F.R.D. at 346). "As the Supreme Court has said, Rule 23(b)(3) class actions can be superior precisely because they facilitate the redress of claims where the costs of bringing individual actions outweigh the expected recovery." *In re U.S. Foodservice Inc. Pricing Litig.*, 729 F.3d 108, 130 (2d Cir. 2013) (quoting *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 617 (1997)).

Turning to Rule 23(b)(3)(C), several considerations weigh in favor of concentrating the litigation in this particular forum. First, the current litigation has been before this Court for nearly three years, since September 2015. In that time, I have made a number of dispositive rulings that govern the claims of all direct purchasers. The parties have thus already litigated several issues that would surely arise in any new case. I also have before me the claims of the indirect purchasers in this case, which I have stayed pending the outcome of this litigation. (Dkt. No. 106.) These considerations make concentrating this litigation here particularly desirable.

Turning to the fourth and most important consideration in the superiority analysis, the manageability of a particular class action is "an issue peculiarly within a district court's discretion." *Adkins v. Morgan Stanley*, 307 F.R.D. 119, 147 (S.D.N.Y. 2015), *aff'd*, 656 F. App'x 555 (2d Cir. 2016) (internal quotation marks omitted) (quoting *Seijas v. Repub. of Argentina*, 606 F.3d 53, 58 (2d Cir. 2010)). This class does not present any unique manageability issues that would preclude certification. As far as classes go, this class is relatively small. Moreover, certification would promote uniformity of decision as to all direct purchasers, without sacrificing procedural fairness. *Id.* at 141.

For the reasons described above, Plaintiffs' motion for class certification is GRANTED.

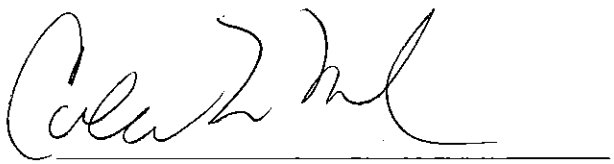
I am certifying a direct purchaser plaintiff class including the 62 members proposed in Plaintiffs' revised list. These include Albertsons LLC; American Health Packaging; Amerisource Bergen; Anda; Associated Pharmacies; Auburn Pharmaceutical; Bellco; Bartell; Bloodworth Wholesale Drugs; Blupax Pharmaceuticals, LLC; Burlington Drug; Capital Wholesale; Cardinal Health; CVS Caremark; Dakota Drug; Discount Drug Mart; DMS; Drogueria Betances; Drogueria Central; Drogueria Cesar Castillo; Drugs Unlimited, Inc.; Express Scripts Inc.; Frank W. Kerr Inc.; Genetco Inc.; Hannaford Brothers; HC Pharmacy Central Inc.; Healthsource Distributors, LLC; HE Butt; HD Smith LLC; Humana, Inc.; Independent Pharmacy Cooperative; Kaiser Permanente; Kerr Drug; Keysource Medical, Inc.; Kroger; Louisiana Wholesale Drug; Major Pharmaceuticals/Rugby Lab; Masters Pharmaceutical Inc.; McKesson; Medco Health Solutions Inc.; Meijer Inc.; Miami Luken; Morris & Dickson; North Carolina Mutual Wholesale Drug; Optumrx Inc.; PBA Health; Peytons; Prescription Supply Inc.; Quest Pharmaceuticals, Inc.; Publix; Richie Pharmaceutical Company; RDC; RX Outreach; Smith; Supervalu Inc.; Tel Drug of PA LLC Joann Christens; The Harvard Group; Top RX LLC; Valley Wholesale; Value Drug; Walmart; Winn Dixie Logistics Inc.

CONCLUSION

This constitutes the decision and order of the Court.

Forest's motion for leave to file a letter of supplemental authority (Dkt. No. 561) is DENIED. The Clerk of the Court is directed to remove the motions at Dkt. Nos. 400, 434, 437, 439, 441, 443, 445, 505, and 561 from the Court's list of pending motions.

Dated: August 7, 2018



Chief Judge

BY ECF TO ALL COUNSEL